

Exhibit B

UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

UNITED STATES OF AMERICA
ex rel. JOHN BURNS,

Plaintiffs,

v.

Case No.

MEDTRONIC, INC., BOSTON SCIENTIFIC
CORPORATION, and ST. JUDE MEDICAL, INC.,

Defendants

8.10 CV 1851-T23
FAJ

FILED
10 AUG 18 PM 3:19
U.S. DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA, FLORIDA

FILED UNDER SEAL
PURSUANT TO 31 U.S.C.
§3730(B)(2)
DO NOT PLACE IN PRESS BOX
OR ENTER ON PACER
SYSTEM

FALSE CLAIMS ACT COMPLAINT AND DEMAND FOR JURY TRIAL

INTRODUCTION

1. John Burns ("Relator") brings this action on behalf of the United States of America against Defendants Medtronic, Inc., Boston Scientific Corporation and St. Jude Medical, Inc., for treble damages and civil penalties for the Defendants' violations of the False Claims Act, 31 U.S.C. §3729 *et seq.*

2. As required by the False Claims Act, 31 U.S.C. §3730(b)(2), Relator has provided previously to the Attorney General of the United States and to the United States Attorney for the Middle District of Florida a statement of all material evidence and information related to the complaint. This disclosure statement is supported by material evidence known to Relator establishing the existence of Defendants' false claims. Because the disclosure statement includes attorney-client communications and work product of Relator's attorneys, and is submitted to the Attorney General and to the United States Attorney in their capacity as potential co-counsel in this litigation, Relator understands this disclosure to be confidential.

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JURISDICTION AND VENUE

3. This action arises under the False Claims Act, 31 U.S.C. §3729 *et seq.* This Court has jurisdiction over this case pursuant to 31 U.S.C. §3732(a) and 3730(b), as well as 28 U.S.C. §1345 and §1331.

4. Venue is proper in this district pursuant to 31 U.S.C. §3732(a), because the acts proscribed by 31 U.S.C. §3729 *et seq.* and complained of herein took place in this district, and is also proper pursuant to 28 U.S.C. §1391(b) and (c) because at all relevant times Defendants transacted business in this district.

THE PARTIES

5. John Burns is a sales representative currently employed by Medtronic, Inc. in Manatee County, Florida. He has been a Medtronic sales representative since 2002 and has worked at Medtronic since 2000. Mr. Burns is licensed as a registered nurse in Florida and worked as a registered nurse between 1995 and 2000. He received an associates degree in nursing from St. Petersburg Junior College in 1995.

6. Mr. Burns served in the United States Army between 1988 and 1992 and in the Florida National Guard between 1992 and 1998 before being honorably discharged as a Sergeant. He served as an Emergency Medical Technician at Brooke Army Medical Center, Fort Sam Houston, Texas.

7. Mr. Burns graduated from a 1000-hour course at the Arrhythmic Technologies Institute (ATTI) in Greenville, South Carolina in 2000 with a certificate in Cardiac Device Technologies.

8. Mr. Burns has received numerous sales awards and recognition during his career at Medtronic. In 2001, Mr. Burns was twice named the Cardiac Rhythm Management National Representative of the Quarter. In 2005, Mr. Burns was named to the Medtronic Cardiac Rhythm

Management President's Club. As recently as May 2010, Mr. Burns was commended for exceeding his sales goal.

9. Medtronic, Inc., based in Minneapolis, Minnesota, is the world's largest medical technology company and is a Fortune 500 company. Its CRDM division developed the first wearable heart pacemaker in 1957. Medtronic is a member of the Advanced Medical Technology Association and a signatory to the July 2009 AdvaMed Code of Ethics.

10. Boston Scientific Corporation is a medical device manufacturer based in Natick, Massachusetts. Boston Scientific acquired competitor Guidant Corporation in 2006. In March 2010, Boston Scientific reached a \$22 million settlement to resolve allegations that Guidant had used post-market studies as vehicles to pay kickbacks to induce physicians to implant Guidant pacemakers and defibrillators. In December 2009, Boston Scientific entered a five-year corporate integrity agreement with the United States Department of Health and Human Services. Boston Scientific Corporation is a member of the Advanced Medical Technology Association and a signatory to the July 2009 AdvaMed Code of Ethics.

11. St. Jude Medical, Inc. is a global medical device company based in Little Canada, Minnesota. St. Jude Medical, Inc. is a member of the Advanced Medical Technology Association and a signatory to the July 2009 AdvaMed Code of Ethics.

12. John Burns is an "original source" within the meaning of 31 U.S.C. § 3730(e)(4)(B), but states that to his knowledge the information contained herein concerning Defendants' False Claims Act violations has not been publicly disclosed.

MEDICARE PROGRAM POLICIES

13. The Medicare program will reimburse providers only for services actually performed by those providers.

14. The Medicare program requires participating providers to maintain true and accurate records supporting the legitimacy of claims submitted for reimbursement.

15. As part of their provider agreements with the Medicare program, Defendants are required to certify that they will comply with federal health care laws, including the Anti-Kickback Act, 42 U.S.C. §1320a-7b.

16. The Anti-Kickback Act prohibits offering, paying, soliciting, or receiving any remuneration in return for or to induce the referral of business paid for by the Medicare and Medicaid programs.

17. Compliance with the Anti-Kickback Act is a condition of payment by the Medicare program. *McNutt v. Haleyville Medical Supplies, Inc.*, 423 F.3d 1256, 1259 (11th Cir. 2005).

18. Violating the Anti-Kickback Act disqualifies a provider from receiving payment from the Medicare program for claims for services obtained through illegal remuneration. *McNutt v. Haleyville Medical Supplies, Inc.*, 423 F.3d 1256, 1259 (11th Cir. 2005).

PACEMAKER AND DEFIBRILLATOR RECHECK BACKGROUND

19. Patients with implanted pacemakers and defibrillators to regulate their heart rhythm need their pacemakers and defibrillators rechecked approximately every three months. Procedure codes for these rechecks are divided into a technical component (“TC”) and a professional component which contains a –26 modifier. These components can be billed to Medicare separately or they can be combined into a global procedure code.

20. For example, the Medicare reimbursement rates for pacemaker and defibrillator equipment rechecks in 2007 were as follows:

CPT Code	Brief Description	2007 Medicare National Payment Rate
	Dual chamber pacemaker, without reprogramming	

93731-TC	Electronic analysis of dual chamber pacemaker system; without reprogramming (technical component)	\$21
93731-26	(professional component)	\$23
93731 (Global)	(global fee)	\$44
Dual chamber pacemaker, with reprogramming		
93732-TC	Electronic analysis of dual chamber pacemaker system; with reprogramming (technical component)	\$22
93732-26	(professional component)	\$48
93732-(Global)	(global fee)	\$70
Single chamber pacemaker, without reprogramming		
93734-TC	Electronic analysis of dual chamber pacemaker system; with reprogramming (technical component)	\$16
93734-26	(professional component)	\$19
93734 (Global)	(global fee)	\$35
Single chamber pacemaker, with reprogramming		
93735-TC	Electronic analysis of dual chamber pacemaker system; with reprogramming (technical component)	\$19
93735-26	(professional component)	\$38
93735 (Global)	(global fee)	\$57
Dual chamber pacemaker transtelephonic monitoring (TTM)		
93733-TC	Electronic analysis of dual chamber pacemaker system; with reprogramming (technical component)	\$31
93733-26	(professional component)	\$9
93733 (Global)	(global fee)	\$40
Single chamber pacemaker transtelephonic monitoring (TTM)		
93736-TC	Electronic analysis of dual chamber pacemaker system; with reprogramming (technical component)	\$28
93736-26	(professional component)	\$8
93736 (Global)	(global fee)	\$36
Single chamber ICD without programming		
93741-TC	Electronic analysis of dual chamber pacemaker system; with reprogramming (technical component)	\$26
93741-26	(professional component)	\$41

93741 (Global)	(global fee)	\$67
Single chamber ICD with programming		
93742-TC	Electronic analysis of dual chamber pacemaker system; with reprogramming (technical component)	\$27
93742-26	(professional component)	\$47
93742 (Global)	(global fee)	\$74
Dual chamber ICD without programming		
93743-TC	Electronic analysis of dual chamber pacemaker system; with reprogramming (technical component)	\$28
93743-26	(professional component)	\$53
93743 (Global)	(global fee)	\$81
Dual chamber ICD with programming		
93744-TC	Electronic analysis of dual chamber pacemaker system; with reprogramming (technical component)	\$27
93744-26	(professional component)	\$61
93744 (Global)	(global fee)	\$88

21. Medtronic's 2007 Cardiac Rhythm Device Management Select Physician Procedure Scenario document clearly warns that "[t]he patient or payer should not be billed for services rendered solely by a manufacturer's representative." **Exhibit 1.**

22. Medtronic's CRDM Field Technical Support Policy dated October 7, 2008 instructs that "field personnel should not fill out 'superbills' or any other clinic paperwork that contains reimbursement information." **Exhibit 2.**

23. On November 5, 2009, John Burns sent an email to John Rader of Medtronic's CRDM Economic Strategies and Solutions asking "if MDT/industry personnel are doing clinic then -26 just needs to be added correct?" **Exhibit 3.** Rader told John Burns "Yes".

24. The July 2009 AdvaMed Code of Ethics instructs that "a Company should not provide free services that eliminate an overhead or other expense that a Health Care Professional

would otherwise of business prudence or necessity have incurred as part of its business operations if doing so would amount to an unlawful inducement." **Exhibit 4.**

COUNT I: CAUSING PHYSICIANS TO PRESENT FALSE CLAIMS IN
VIOLATION OF 31 U.S.C. § 3729(A)(1)
(ALL DEFENDANTS)

25. Relator realleges and incorporates by reference paragraphs 1 through 24.

26. Defendants caused physicians to submit false and fraudulent claims to Medicare for the technical component of pacemaker and defibrillator equipment checks which the physicians did not perform.

27. Since he started working at Medtronic in 2000, Mr. Burns has performed rechecks of Medtronic pacemakers and defibrillators for the patients of physician clients. Prior to 2009, this work was billed to the Medicare program as the technical component ("TC") of such procedure codes as 93731-TC; 93732-TC; 93734-TC; 93735-TC; 93733-TC; 93736-TC; 93741-TC; 93742-TC; 93742-TC; 93743-TC, and 93744-TC. In 2009 and thereafter, this work was billed to the Medicare program as 93288-TC; 93279-TC; 93280-TC, and 93281-TC.

28. Rather than billing the Medicare program for the hundreds of pacemaker and defibrillator equipment rechecks performed by its sales representatives each year, Medtronic has routinely allowed cardiologists who implant Medtronic pacemakers and defibrillators to have those devices rechecked for free and has routinely enabled those cardiologists to fraudulently bill Medicare under global procedure codes so that they could be paid by Medicare for performing technical component work which they had not done. Medtronic representatives did so (1) by performing technical component recheck work using Medtronic's own equipment without billing Medicare; and (2) by completing superbills falsely indicating that cardiologists that performed global procedure codes for technical component work they had not done, while knowing from cardiologists' superbills that cardiologists were billing only global procedure codes.

29. Cardiologists in Manatee County, Florida who routinely billed Medicare for pacemaker and defibrillator equipment rechecks done by John Burns include:

Bradenton Heart Center¹
2010 59th Street West
Suite 4200
Bradenton, Florida 34209
(941) 794-3999

Dr. Raj T. Rajan²
Dr. Asad Sawur³
Dr. Niranjana Seshadri⁴
Dr. Jagan Akella⁵
Dr. Christopher Davis⁶
Austin Eversile, ARNP

Dr. Lawrence C. Hasara⁷
2225 59th Street West
Suite D
Bradenton, Florida 34209
(941) 761-8955

Lakewood Ranch Cardiovascular Center⁸
6310 Health Park Way
Suite 230
Bradenton, Florida 34202

Dr. Eric E. Calderon
Dr. Jason Okuhara

Pinnacle Cardiovascular Consultants
315 75th Street West
Bradenton, Florida 34209
(941) 795-3606

Advanced Cardiology⁹
4900 Manatee Avenue West
Suite 201
Bradenton, Florida 34209

Dr. John Lourie

¹ See redacted Bradenton Heart Center superbills attached as **Exhibit 5**, including for Medicaid patient MS on 2/18/09 and patient SS on 1/12/10.

² Dr. Rajan founded Bradenton Heart Center. John Burns had conversations with Dr. Rajan about training an office employee so Bradenton Heart Center could bill globally for equipment rechecks. In approximately 2007 or 2008, Mr. Burns talked to Dr. Rajan and told Dr. Rajan he should not be billing for the technical component of pacemaker rechecks. The day after this conversation, Dr. Rajan's secretary called Mr. Burns to tell Burns that Dr. Rajan no longer needed Burns to do equipment rechecks for Dr. Rajan's patients with Medtronic devices.

³ Dr. Sawur has moved to Tampa.

⁴ Dr. Seshadri has moved to Heart Care in Lakewood Ranch.

⁵ Dr. Akella now has his own practice in Bradenton. Dr. Akella's superbills list only global codes for representatives to check and do not list the -26 professional component modifier as a billing option.

⁶ Dr. Davis currently works at Bradenton Heart Center.

⁷ See redacted Dr. Hasara superbills attached as **Exhibit 6** for Medicare patient VZ on 3/10/10 and Medicare patient MM on 5/27/09.

⁸ See redacted Lakewood Ranch Cardiovascular Center superbill attached as **Exhibit 7** for Medicare/Medicaid patient MO on 9/16/09.

⁹ See redacted Advanced Cardiology superbills attached as **Exhibit 8** for Medicare patient MC on 11/4/09, for Medicare patient VC on 7/28/10, for Medicare patient CC on 6/16/10, for Medicare patient LB on 12/3/08, and for Medicare patient JL on 1/28/09.

Aldrich Cardiovascular Institute
7978 Cooper Creek Blvd.
Suite 105
Bradenton, Florida 34201
(941) 359-8900

Dr. Martin Aldrich

Heart and Vascular Center¹⁰
2101 61st Street West
Bradenton, Florida 34209

Dr. Joseph Pace

30. Medtronic has been doing free pacemaker rechecks and enabling cardiologists to fraudulently bill Medicare for that work for at least the past ten years John Burns has worked for Medtronic. The conduct Mr. Burns has observed in Manatee County he also observed in Naples, Florida in 2001-2002 and in North Carolina in 2000-2001.

31. John Burns knows that Medtronic's competitors St. Jude and Boston Scientific also performed pacemaker and defibrillator equipment rechecks and enabled cardiologists to fraudulently bill Medicare for that work. Jim Motzenbecker, a former St. Jude employee who worked in the Venice-North Port area, told Mr. Burns that St. Jude engaged in the same conduct as Medtronic. Gordon Ware and Mike Miller also have told Mr. Burns that St. Jude is still currently engaging in the same conduct as Medtronic.

32. Steve Zinn and Rich Merrill have told Mr. Burns that Boston Scientific is still currently engaging in the same conduct as Medtronic. Mr. Burns also obtained **Exhibit 10** from Dr. Joseph Pace's Heart and Vascular Center in Bradenton which was left by a Boston Scientific sales representative. This form shows that Boston Scientific was encouraging cardiologists to bill only global CPT codes which include technical component (TC) work done by Boston Scientific.

33. Moreover, John Burns has seen numerous superbills completed by Boston Scientific and St. Jude representatives for equipment rechecks on which those representatives

¹⁰ See redacted Heart and Vascular Center superbills attached as **Exhibit 9** for Medicare patient CC on 7/27/10, for Medicare patient MW on 7/27/10, for Medicare patient ET on 7/27/10 and for Medicare patient JS on 7/14/10.

checked global codes which falsely indicated that the cardiologist had performed the technical component work.

COUNT II: CAUSING PHYSICIANS TO PRESENT FALSE CLAIMS IN
VIOLATION OF 31 U.S.C. §3729(A)(1)
(ALL DEFENDANTS)

34. Relator realleges and incorporates by reference paragraphs 1 through 24.

35. Defendants caused cardiologists to submit false and fraudulent claims to Medicare for the technical component of pacemaker and defibrillator equipment rechecks which Defendants performed in violation of the Anti-Kickback Act in return for those physicians selecting those companies as suppliers of pacemakers and defibrillators.

36. John Burns, his Medtronic colleagues, and his former Medtronic colleagues who moved to Boston Scientific and St. Jude all understood that they were performing pacemaker and defibrillator equipment rechecks for cardiologists without billing Medicare for that work in order to ensure that those cardiologists continued to implant their company's pacemakers and defibrillators.

37. Jim Motzenbecker told Mr. Burns that St. Jude did the same things for the same reason. The amount of unbilled pacemaker and defibrillator equipment recheck work performed by Medtronic, Boston Scientific and St. Jude is substantial. Mr. Burns personally performed between 10 and 30 pacemaker and defibrillator equipment rechecks per week. The economic reason to do all this unbilled work for free and to enable the referring cardiologists to bill Medicare and get paid for work they never did was to provide a means of disguised remuneration to cardiologists in order to induce continued future implantations of their company's pacemakers and defibrillators by the benefited cardiologist.

38. Mr. Burns knows of one cardiologist, Dr. Joseph Pace, who used both Medtronic and Boston Scientific for free pacemaker equipment rechecks which he billed to Medicare. All

the Defendants use their willingness to provide disguised remuneration in the form of pacemaker and defibrillator equipment rechecks which referring physicians can bill to Medicare as a means of retaining and/or expanding their market share for implanted pacemakers and defibrillators.

**COUNT III: CAUSING PHYSICIANS TO PRESENT FALSE CLAIMS IN
VIOLATION OF 31 U.S.C. § 3729(A)(1)
(ALL DEFENDANTS)**

39. Relator realleges and incorporates by reference paragraphs 1 through 24.

40. Defendants caused physicians to submit false and fraudulent claims to Medicare for the technical component of pacemaker and defibrillator equipment rechecks by completing billing forms for cardiologists which enabled those physicians to bill Medicare despite the fact that Defendants knew the physician supervision requirements necessary for those claims had not been met.

41. As the January 23, 2007 letter attached as **Exhibit 11** from CMS Deputy Director Terrence Key to Dr. Dwight Reynolds, President of the Heart Rhythm Society, states, the technical components for the 93731, 93734, 93741, 93742, 93743, 93744 and 93745 procedure codes require direct supervision by a physician. Direct supervision requires that a physician be physically present in the building when those procedures are performed.

42. Many cardiologists billed Medicare for these technical components when they were not in fact on the premises and able to provide the required direct supervision.

43. John Burns knows that these practices bill for technical components of pacemaker and defibrillator equipment rechecks always or often done without direct supervision:

Bradenton Heart Center
2010 59th Street West
Suite 4200
Bradenton, Florida 34209
(941) 794-3999

Dr. Raj T. Rajan

Lakewood Ranch Cardiovascular Center Dr. Eric E. Calderon
6310 Health Park Way
Suite 230
Bradenton, Florida 34202

Healthcare America¹¹ Dr. Enrique Rivera
3501 Cortez Road West
Bradenton, Florida 34202

COUNT IV: CAUSING PHYSICIANS TO PRESENT FALSE CLAIMS IN
VIOLATION OF 31 U.S.C. § 3729(A)(1)
(BOSTON SCIENTIFIC AND ST. JUDE DEFENDANTS)

44. Relator realleges and incorporates by reference paragraphs 1 through 24.

45. Defendants Boston Scientific and St. Jude cause physicians to submit false and fraudulent claims to Medicare by inducing physicians to purchase pacemaker equipment from those companies by providing free training courses for non-invasive cardiologists in Mexico and Europe.

46. John Burns knows that both Boston Scientific and St. Jude have provided free training courses in exotic locations such as Mexico (St. Jude and Boston Scientific) and Europe (St. Jude). These courses were designed to enable non-invasive cardiologists to learn how to implant pacemakers. These courses were held in exotic locations so that the attending cardiologists could get training unavailable in the United States to permit them to obtain hospital privileges to implant defibrillators.

WHEREFORE, Relator respectfully requests this Court enter judgment against Defendants and order:

(a) That the United States be awarded damages in the amount of three times the damages sustained by the United States because of the false and fraudulent claims alleged within this Complaint, as the False Claims Act, 31 U.S.C. §3729, provides;

¹¹ See redacted Healthcare America superbill attached as **Exhibit 12** for Medicare patient DM on 10/22/09.

(b) That civil penalties of \$11,000 be imposed for each and every false and fraudulent claim that Defendants presented to the United States;

(c) That pre and post-judgment interest be awarded, along with reasonable attorneys' fees, costs and expenses which Relator necessarily incurred in bringing and pressing this case;

(d) That the Court grant permanent injunctive relief to prevent any recurrence of the False Claims Act violations for which redress is sought in this Complaint;

(e) That the Relator be awarded the maximum amount allowed pursuant to the False Claims Act; and

(f) That the Court award such other and further relief as it deems proper.

DEMAND FOR JURY TRIAL

Relator, on behalf of himself and the United States, demands a jury trial on all claims alleged herein.

Respectfully submitted,



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Facsimile: (813) 225-1921

Attorneys for *Qui Tam* Relator

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing *False Claims Act Complaint and Demand for Jury Trial* has been furnished by hand delivery to: **A. Brian Albritton**, United States Attorney, United States Attorney's Office, 400 N. Tampa Street, Ste 3200, Tampa, FL 33602 and **Civil Process Clerk**, 400 North Tampa Street, Suite 3200, Tampa, Florida 33602; and by Federal Express to **Eric Holder**, United States Attorney General, Dept. of Justice, 950 Pennsylvania Ave., N.W., Washington, D.C. 20530-001 on this 18th day of August 2010.



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CARDIAC RHYTHM DISEASE MANAGEMENT: SELECT PHYSICIAN PROCEDURE SCENARIOS

2007 Medicare National Physician Payment Rates

These coding suggestions and coverage guidelines do not replace seeking coding advice from the payer and/or your coding staff. The ultimate responsibility for correct coding lies with the provider of services. Please contact your local payer for interpretation of the appropriate codes to use for specific procedures. Medtronic makes no guarantee that the use of this information will prevent differences of opinion or disputes with Medicare or other third party payers as to the correct form of billing or the amount that will be paid to providers of service.

DEVICE IMPLANT, UPGRADE, AND REPLACEMENT SCENARIOS

CPT [®] Code	Brief Description	2007 Medicare National Payment Rate ¹
Single chamber pacemaker implant; atrial lead		
33206	Insert single chamber pacemaker (generator and leads)	\$445
71090-26	Fluoroscopy	\$28
	Payment Total	\$473
Single chamber pacemaker implant; ventricular lead		
33207	Insert single chamber pacemaker (generator and leads)	\$518
71090-26	Fluoroscopy	\$28
	Payment Total	\$546
Dual chamber pacemaker implant		
33208	Insert dual chamber pacemaker (generator and leads)	\$485
71090-26	Fluoroscopy	\$28
	Payment Total	\$513
Dual chamber pacemaker generator replacement		
33213	Insert dual chamber pacemaker generator	\$380
33233-51	Removal of pacemaker generator (Paid at 50%)	\$123
	Payment Total	\$503
CRT-P implant		
33208	Insert dual chamber pacemaker (generator and leads)	\$485
+33225	Insert LV lead	\$436
71090-26	Fluoroscopy	\$28
	Payment Total	\$949
Upgrade dual chamber pacemaker to CRT-P		
33213	Insert dual chamber pacemaker generator	\$380
+33225	Insert LV lead	\$436
33233-51	Removal of pacemaker generator (Paid at 50%)	\$123
71090-26	Fluoroscopy	\$28
	Payment Total	\$967

CPT Code	Brief Description	2007 Medicare National Payment Rate
Upgrade dual chamber pacemaker to CRT-D		
+33225	Insert LV lead	\$436
33233-51	Removal of pacemaker generator (Paid at 50%)	\$123
33240	Insert dual chamber ICD generator	\$456
71090-26	Fluoroscopy	\$28
	Payment Total	\$1,043
Insert epicardial lead and CRT-P system		
33203	Insertion of epicardial electrode(s); endoscopic approach	\$766
33208-51	Insert dual chamber pacemaker (generator and leads) (Paid at 50%)	\$243
+33225	Insert LV lead	\$436
71090-26	Fluoroscopy	\$28
	Payment Total	\$1,473
ICD generator implant		
33249	Implant single or dual chamber ICD defibrillator (generator and leads)	\$878
71090-26	Fluoroscopy	\$28
93641-26	Test generator/leads at implant	\$313
	Payment Total	\$1,219
ICD generator replacement		
33240	Insert single or dual chamber ICD generator	\$456
33241-51	Removal of single or dual chamber ICD generator (Paid at 50%)	\$115
93641-26	Test generator/leads at implant	\$313
	Payment Total	\$884
CRT-D implant		
+33225	Insert LV lead	\$436
33249	Implant single or dual chamber ICD defibrillator (generator and leads)	\$878
71090-26	Fluoroscopy	\$28
93641-26	Test generator/leads at implant	\$313
	Payment Total	\$1,655

CPT Code	Brief Description	2007 Medicare National Payment Rate ¹
Upgrade dual chamber ICD to CRT-D		
+33225	Insert LV lead	\$436
33240	Insert single or dual chamber ICD generator--	\$456
33241-51	Removal of single or dual chamber ICD generator (Paid at 50%)	\$115
71090-26	Fluoroscopy	\$28
93641-26	Test generator/leads at implant	\$313
	Payment Total	\$1,348

Implant patient-activated cardiac event recorder		
33282	Implant patient-activated cardiac event recorder	\$324

CPT Code	Brief Description	2007 Medicare National Payment Rate
Insert epicardial lead and CRT-D system		
33203-51	Insertion of epicardial electrode(s) endoscopic approach (Paid at 50%)	\$383
+33225	Insert LV lead	\$436
33249	Implant single or dual chamber ICD defibrillator (generator and leads)	\$878
71090-26	Fluoroscopy	\$28
93641-26	Test generator/leads at implant	\$313
	Payment Total	\$2,038

Remote patient-activated cardiac event recorder		
33284	Remove patient-activated cardiac event recorder	\$241

DEVICE FOLLOW-UP

CPT Code	Brief Description	2007 Medicare National Payment Rate
Dual chamber pacemaker, without reprogramming		
93731-26	Electronic analysis of dual chamber pacemaker system; without reprogramming (technical component)	\$21
93731-26	(professional component)	\$23
93731 (Global)	(global fee)	\$44

Dual chamber pacemaker, with reprogramming		
93732-26	Electronic analysis of dual chamber pacemaker system; with reprogramming (technical component)	\$22
93732-26	(professional component)	\$48
93732 (Global)	(global fee)	\$70

Single chamber pacemaker, without reprogramming		
93734-26	Electronic analysis of single chamber pacemaker system; without reprogramming (technical component)	\$16
93734-26	(professional component)	\$19
93734 (Global)	(global fee)	\$35

Single chamber pacemaker, with reprogramming		
93735-26	Electronic analysis of single chamber pacemaker system; with reprogramming (technical component)	\$19
93735-26	(professional component)	\$38
93735 (Global)	(global fee)	\$57

Dual chamber pacemaker transtelephonic monitoring (TTM)		
93733-26	Electronic analysis of dual chamber pacemaker system; with reprogramming (technical component)	\$31
93733-26	(professional component)	\$9
93733 (Global)	(global fee)	\$40

Single chamber pacemaker transtelephonic monitoring (TTM)		
93736-26	Electronic analysis of single chamber pacemaker system; with reprogramming (technical component)	\$28
93736-26	(professional component)	\$8
93736 (Global)	(global fee)	\$36

CPT Code	Brief Description	2007 Medicare National Payment Rate
Electronic analysis of insertable loop recorder		
93727	Electronic analysis of insertable loop recorder (ILR) system	\$30

Single chamber ICD, without reprogramming		
93741-26	Electronic analysis of pacing cardioverter-defibrillator, single chamber or wearable ICD system; without reprogramming (technical component)	\$26
93741-26	(professional component)	\$41
93741 (Global)	(global fee)	\$67

Single chamber ICD, with reprogramming		
93742-26	Electronic analysis of pacing cardioverter-defibrillator, single chamber ICD system; with reprogramming (technical component)	\$27
93742-26	(professional component)	\$47
93742 (Global)	(global fee)	\$74

Dual chamber ICD, without reprogramming		
93743-26	Electronic analysis of pacing cardioverter-defibrillator, dual chamber ICD system; without reprogramming (technical component)	\$28
93743-26	(professional component)	\$53
93743 (Global)	(global fee)	\$81

Dual chamber ICD, with reprogramming		
93744-26	Electronic analysis of pacing cardioverter-defibrillator, dual chamber ICD system; with reprogramming (technical component)	\$27
93744-26	(professional component)	\$61
93744 (Global)	(global fee)	\$88

Biventricular Pacemaker and Defibrillator Electronic Analysis Codes:
 Currently, there are no codes specific to analysis and reprogramming of a biventricular device. If a patient has a right and left ventricular lead, single chamber follow-up codes should be considered. If a patient has atrial and ventricular leads, dual chamber follow-up should be considered. Check with your Medicare contractor or other payer for appropriate coding.

The patient or payer should not be billed for services rendered solely by a manufacturer's representative.¹ Additional restrictions may apply; contact your local contractor/payer for interpretation of applicable policies.

¹ Hayes J, Aknavorian R, Maloney JD; NASPE. North American Society of Pacing and Electrophysiology. The role(s) of the industry-employed allied professional. *Pacing Clin*

ECHOCARDIOGRAPHY PROCEDURES

CPT Code	Brief Description	2007 Medicare National Payment Rate ²
Echocardiography complete		
93307-TC	Echocardiography, transthoracic, real time with image documentation (2D) with or without M-mode recording; complete (technical component)	\$150
93307-26	(professional component)	\$47
93307 (Global)	(global fee)	\$197

Doppler echocardiography complete		
+93320-TC	Doppler Echocardiography, pulsed wave and/or continuous wave with spectral display; complete (technical component)	\$67
+93320-26	(professional component)	\$20
+93320 (Global)	(global fee)	\$87

Doppler color flow		
+93325-TC	Doppler Echocardiography, color flow velocity mapping (technical component)	\$96
+93325-26	(professional component)	\$4
+93325 (Global)	(global fee)	\$100

CPT Code	Brief Description	2007 Medicare National Payment Rate
Echocardiography follow-up or limited study		
93308-TC	Echocardiography, transthoracic, real time with image documentation (2D) with or without M-mode recording; follow-up or limited study (technical component)	\$82
93308-26	(professional component)	\$28
93308 (Global)	(global fee)	\$110

Doppler echocardiography follow-up or limited study		
+93321-TC	Doppler Echocardiography, pulsed wave and/or continuous wave with spectral display; follow-up or limited study (technical component)	\$40
+93321-26	(professional component)	\$8
+93321 (Global)	(global fee)	\$48

ELECTROPHYSIOLOGY PROCEDURES

CPT Code	Brief Description	2007 Medicare National Payment Rate
Comprehensive EP evaluations		
93619-26	Comprehensive EP eval with right atrial pacing and recording, right ventricular pacing and recording, His bundle recording, including insert/reposition of multiple electrode catheters, without induction or attempted induction of arrhythmia	\$396
93620-26	Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of arrhythmia; with right atrial pacing and recording, right ventricular pacing and recording, His bundle recording	\$623
+93621-26	Comprehensive EP eval including insertion/reposition of multiple electrode catheters with induction or attempted induction of arrhythmia; with left atrial pacing and recording from coronary sinus or left atrium	\$111
+93622-26	Comprehensive EP eval including insertion/reposition of multiple electrode catheters with induction or attempted induction of arrhythmia; with left ventricular pacing and recording	\$164

CPT Code	Brief Description	2007 Medicare National Payment Rate
Recording and mapping		
93600-26	Bundle of His recording	\$113
93602-26	Intra-atrial recording	\$113
93603-26	Right ventricular recording	\$113
+93609-26	Intraventricular and/or intra-atrial mapping of tachycardia site(s) with catheter manipulation to record from multiple sites to identify origin of tachycardia	\$265
93610-26	Intra-atrial pacing	\$160
93612-26	Intraventricular pacing	\$160
+93613	Intracardiac electrophysiologic 3-D mapping	\$372
93615-26	Esophageal recording of atrial electrogram with or without ventricular electrogram(s)	\$47
93616-26	Esophageal recording of atrial electrogram with or without ventricular electrogram(s); with pacing	\$70
93618-26	Induction of arrhythmia by electrical pacing	\$226
+93623	Programmed stimulation and pacing after IV drug infusion	\$151
93624-TC	EP follow-up study with pacing and recording to test effectiveness of therapy, including induction of arrhythmia (technical component)	\$80
93624-26	(professional component)	\$264
93624 (Global)	(global fee)	\$344
93631-26	Intra-operative epicardial and endocardial pacing and mapping to localize the site of tachycardia	\$401
93660-TC	Evaluation of cardiovascular function with tilt table evaluation (technical component)	\$68
93660-26	(professional component)	\$97
93660 (Global)	(global fee)	\$165
+93662-26	Intracardiac echocardiography during	\$145

ICD DEVICE TESTING

CPT Code	Brief Description	2007 Medicare National Payment Rate ²
ICD follow-up testing		
93642-TC	EP evaluation of single or dual chamber ICD (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing and pacing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters) (technical component)	\$265
93642-26	(professional component)	\$260
93642 (Global)	(global fee)	\$525

CPT Code	Brief Description	2007 Medicare National Payment Rate
Intra-operative device testing		
93640-26	EP evaluation of single or dual chamber ICD leads including defibrillation threshold evaluation (induction of arrhythmia, evaluation of sensing and pacing for arrhythmia termination) at time of initial implantation or replacement (professional component)	\$186
93641-26	EP evaluation of single or dual chamber ICD leads including defibrillation threshold evaluation (induction of arrhythmia, evaluation of sensing and pacing for arrhythmia termination) at time of initial implantation or replacement; with testing of single or dual chamber ICD pulse generator (professional component)	\$313

CATHETER ABLATIONS AND CARDIOVERSIONS

CPT Code	Brief Description	2007 Medicare National Payment Rate
Catheter ablations		
93650	Intracardiac catheter ablation of AV node function with or without temporary pacemaker placement	\$568
93651	Intracardiac catheter ablation of arrhythmogenic focus; for treatment of supraventricular tachycardia by ablation of fast or slow atrioventricular pathways, accessory atrioventricular connections or other atrial foci, singly or in combinations	\$860
93652	Intracardiac catheter ablation of arrhythmogenic focus; for treatment of ventricular tachycardia	\$935

CPT Code	Brief Description	2007 Medicare National Payment Rate
Cardioversions		
92960	Cardioversion, elective, electrical conversion of arrhythmia; external (Facility Rate)	\$127
92961	Cardioversion, elective, electrical conversion of arrhythmia; internal (separate procedure)	\$250

References

¹ Current Procedural Terminology (CPT) is copyright 2006 American Medical Association. All Rights Reserved. No fee schedules, basic units, relative values, or related listings are included in CPT. The AMA assumes no liability for the data contained herein. Applicable FARS/DFARS restrictions apply to government use.

Codes indicated with a + symbol in front of them are "add-on" codes. These procedures are always performed in addition to the primary procedure, and are never reported as stand-alone codes. Modifier -26 entails the professional component of procedures that are a combination of a professional and a technical component. Modifier -51 represents a multiple procedure other than evaluation and management services performed at the same session by the same provider.

² 2007 Medicare national payment rates per Federal Register, Vol 71, No. 231, published 12-1-06 and CMS Transmittal 258, December 22, 2006. Rates effective 1-1-07 through 12-31-07.

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MEDTRONIC CRDM FIELD TECHNICAL SUPPORT POLICY

BACKGROUND

Medtronic products use highly complex technologies to maximize therapeutic device benefits and allow for on-going monitoring of patients. These sophisticated devices contain numerous features that are programmed uniquely to benefit individual patients. Medtronic personnel in the field sales organization ("Field Personnel") are highly trained on the operation and safe and effective use of these devices. They play an important role in patient care by providing product-related technical support and education to physicians and other health professionals for the benefit of patients.

This policy is effective on October 7, 2008 and is intended to provide Field Personnel with guidance on the appropriate types of technical support and education they may provide. This policy supersedes both the Sales Operating Policy and Procedure ("SOPP") effective June 18, 2007 and the Q&A on the SOPP dated July 27, 2007.

POLICY

1. General Scope of Duties. Field Personnel Should

- Provide technical support under the direction and supervision of a physician to enhance patient care and contribute to the safe and effective use of Medtronic devices;
- Know and follow applicable hospital and physician practice group policies and procedures when providing technical support;
- Provide technical support that involves programming of medical devices only under a written order of a physician familiar with implantable devices (or a verbal order that is followed by a written order placed in the patient's chart);
- Sign or initial the forms/strips before placing them into the patient's chart or record and otherwise make clear that Medtronic Field Personnel have provided the technical support or filled out the form(s)
- Offer, where appropriate, healthcare providers appropriate training on the interrogation and programming of Medtronic implantable devices; and
- Inform patients that they are employees of Medtronic.

2. Reimbursement. Field Personnel Should

- Provide only Medtronic-approved reimbursement educational materials to healthcare providers related to the appropriate coding and billing for implantable device follow-ups;
- Not fill out "superbills" or any other clinic paperwork that contains reimbursement information; and
- Direct health care providers with additional questions about coding and billing for CRDM-related procedures and products to the reimbursement hot line (866-877-4102 press 1 or local 952-345-6400).

3. Patient Data. Field Personnel

- Should adhere to regulations pertaining to patient privacy, as well as clinic and hospital policies with respect to access and handling of patient data;
- Should use care in handling, transporting and securing patient data in any form, and promptly report theft or loss of patient data stored on Medtronic electronic equipment (e.g. laptops, Programmers, PDAs, etc.) to the Field Services Call Center (763-514-9920); and
- May, at the request of the healthcare provider, enter information related to the patient's device into EMR, PaceArt System or CareLink Network. Field Personnel may also, upon request of the health care provider, record their technical observations regarding the device check and device performance on appropriate forms and assist in enrolling patients in CareLink.

EXHIBIT 2

7. October 2008

4. Field Personnel Should Not

- Provide technical support for device follow ups when they know a physician is not present in the office suite. However, Field Personnel may provide such support in less frequent situations when, in their judgment, it is in the patients' best interests to do so. Field Personnel should seek guidance from their local management or CRDM's Compliance and Ethics Officer in those situations when they are asked to provide technical support for device follow ups when they know a physician, on a regular and recurrent basis, is not present in the office suite when technical support by Field Personnel is being provided;
- Perform administrative duties typically expected to be performed by physician office staff, such as scheduling patient appointments or pulling patient records; however it is acceptable to call patients back from the waiting room;
- Practice medicine, such as diagnosing or treating illnesses, or taking patient vitals or health histories, even if otherwise licensed to do so;
- Hold themselves out to be health care professionals in the scope of their duties for Medtronic;
- Turn-off high power detection or therapies unless a licensed medical professional is present when the therapy is turned off and a physician has issued a written order that the therapy be turned off (or a verbal order that is followed by a written order placed in the patient's chart); or
- Turn-off low power therapies or program to unusually low settings in patients who are dependent on the pacemaker to sustain life, whether or not authorized by a physician.

5. Non-Medtronic Devices. Field Personnel Should Not

Provide technical support in connection with device checks of other manufacturers' devices. However, when requested to do so by a physician, Field Personnel may provide such support in less frequent situations, when in their judgment, it is in the best interest of the patient to do so. No Field Personnel should provide technical support in connection with interrogating or reprogramming another manufacturer's device unless he or she feels comfortable doing so. Field Personnel should reprogram another manufacturer's device infrequently and only under the direction and supervision of a physician.

6. Technical Support Outside the Clinical Setting. Field Personnel May

Provide technical support outside the clinical setting, including in a patient's home, a nursing home or a hospice setting, provided a licensed medical professional is present for the technical support, a physician has issued a written order for the technical support or a verbal order that is followed by a written order that is placed in the patient's chart, and the Field Personnel feels comfortable in doing so.

QUESTIONS ABOUT THE POLICY

Questions or concerns about this policy generally should be raised locally since, in most cases, your manager is the best place to go for an accurate and prompt response. If your manager is unable to respond to your concern, you are uncomfortable going to your manager, or local resolution does not make sense because of the issue or people involved, you should contact the National Service Director (763-526-0874) or the CRDM Office of Ethics and Compliance (763-526-1253).

Conversations to talk through questions are usually best, but there may be some times when you are uncomfortable talking to someone in person and wish to remain anonymous. You can anonymously raise any concern through the Medtronic Voice Your Concern line at 1-800-488-3125 or <https://www.voiceyourconcernline.com>.

Burns, John [Pacing Sal]

From: Burns, John [Pacing Sal]
Sent: Thursday, November 05, 2009 9:39 AM
To: Rader, John
Subject: RE: coding

if MDT/industry personel are doing clinic then -26 just needs to be added correct?

From: Rader, John
Sent: Thursday, November 05, 2009 5:47 AM
To: Burns, John [Pacing Sal]
Subject: RE: coding

Hi John, here is the physician services lab sheet for the customers review. Pacers are on the front and ICDs on the back.. I do not see 93296 which is the technical code for CareLink for either pacers/ICDs, need to add that. Are they doing OptiVol? Do not see the codes for that. Check out the lab sheet, it is a great guide for customers.

John Rader
Medtronic, Inc.
Economic Solutions and Strategy
407-791-4369

From: Burns, John [Pacing Sal]
Sent: Wednesday, November 04, 2009 5:28 PM
To: Rader, John
Subject: coding

Hey would this be a sufficent coding sheet for a office?

Pacemakers

93288- pm device eval in person
93279-pm device program eval, single
93280- pm device program eval, dual
93281-pm device program multiple lead
93294-pm device interrrogate remote

ICD's

93289- ICD device interrogation
93282- ICD device program eval, single
93283-ICD device program rval, dual
93284-ICD device program eval, multiple lead
93295-ICD device interrogate remote

EXHIBIT 3

7/26/2010

March 8, 2010

Dear Health Care Professional:

We write collectively to provide you important information about AdvaMed's newly updated Code of Ethics which has been adopted by our companies.

AdvaMed's updated and more rigorous Code of Ethics reflects our industry's commitment to openness, transparency and high ethical standards. The Code provides additional clarity on permitted and prohibited industry interactions with health care providers. It became effective July 1, 2009.

As a community, we have all agreed that our companies and all of our company representatives will abide by the Code in our dealings with you. We have included for your reference a handbook entitled: Deciphering the Code: A guide to the shared principles, policies and practices governing the CRM industry, to provide an overview of the new Code, new standards, and additional resources if you have questions.

Hank Kucheman



Group President, CRV
Boston Scientific Corporation

Eric S. Fain, M.D.



President, Cardiac Rhythm
Management Division
St. Jude Medical

Dan Hackman



Senior Vice President
U.S. Cardiac Rhythm Management
Sorin Group

Jake Langer



President
Biotronik, Inc.

Pat Mackin



Sr. Vice President and President
Cardiac Rhythm Disease Management
Medtronic, Inc.

EXHIBIT 4



CODE OF ETHICS ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS

ADOPTED BY THE ADVANCED MEDICAL TECHNOLOGY ASSOCIATION

I. Preamble: Goal and Scope of AdvaMed Code

The Advanced Medical Technology Association ("AdvaMed") represents companies that develop, produce, manufacture, and market medical products, technologies and related services and therapies used to diagnose, treat, monitor, manage and alleviate health conditions and disabilities ("Medical Technologies") in order to enable patients to live longer and healthier lives (collectively "Companies," and individually "Company"). AdvaMed is dedicated to the advancement of medical science, the improvement of patient care, and, in particular, the contributions that high quality, innovative Medical Technologies make toward achieving these goals. AdvaMed recognizes the obligation to facilitate ethical interactions between Companies and those individuals or entities involved in the provision of health care services and/or items to patients, which purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Companies' Medical Technologies in the United States ("Health Care Professionals").

Medical Technologies

Medical Technologies are often highly dependent upon "hands on" Health Care Professional interaction from beginning to end—unlike drugs and biologics, which act on the human body by pharmacological, immunological or metabolic means. For example, implantable Medical Technologies are often placed in the human body to replace or strengthen a body part. Surgical Medical Technologies often serve as extensions of a physician's hands. In other circumstances, Medical Technologies are noninvasive reagents, instrumentation and/or software to aid in the diagnosis, monitoring and treatment decisions made by Health Care Professionals. Some Medical Technologies work synergistically with other technologies, or are paired with other products that deploy devices in the safest and most effective manner. Many Medical Technologies require technical support during and after deployment.

Interactions with Health Care Professionals

The scope of beneficial interactions between Health Care Professionals and Companies is broad and includes interactions intended to:

- *Promote the Advancement of Medical Technologies.* Developing and improving cutting edge Medical Technologies are collaborative processes between Companies and Health

Care Professionals. Innovation and creativity are essential to the development and evolution of Medical Technologies, which often occur outside a Company's laboratory.

- *Enhance the Safe and Effective Use of Medical Technologies.* The safe and effective use of sophisticated electronic, *in vitro* diagnostic, surgical, or other Medical Technologies often requires Companies to provide Health Care Professionals appropriate instruction, education, training, service and technical support. Regulators often require this type of training as a condition of product approval.
- *Encourage Research and Education.* Companies' support of *bona fide* medical research, education, and enhancement of professional skills improves patient safety and increases access to Medical Technologies.
- *Foster Charitable Donations and Giving.* Companies make monetary and Medical Technology donations for charitable purposes, such as supporting indigent care, as well as patient and public education. This increases access to—as well as the quality of—care and treatment in patient populations that may not otherwise be reached.

The Purpose of the Code of Ethics

AdvaMed recognizes that Health Care Professionals' first duty is to act in the best interests of patients. Companies can serve the interests of patients through beneficial collaborations with Health Care Professionals. To ensure that these collaborative relationships meet high ethical standards, they must be conducted with appropriate transparency and in compliance with applicable laws, regulations and government guidance. AdvaMed recognizes the obligation to facilitate ethical interactions between Companies and Health Care Professionals in order to ensure that medical decisions are based on the best interests of the patient. The ethical principles that govern these interactions are the subject of this Code of Ethics.¹ To that end, AdvaMed restates and amends its Code of Ethics and Frequently Asked Questions (collectively "Code of Ethics" or "Code"), effective July 1, 2009.

II. Code of Ethics Compliance

All Companies are strongly encouraged to adopt this Code and to implement an effective compliance program – one which includes policies and procedures that foster compliance with the Code with respect to their interactions with Health Care Professionals related to Medical Technologies. A Company that adopts the Code is strongly encouraged to submit to AdvaMed an annual certification that the Company has adopted the Code and has implemented an effective compliance program. This certification must be signed by the Company's Chief Executive Officer and Chief Compliance Officer or individuals with equivalent responsibilities within the certifying Company. AdvaMed will publish on its website a list of those Companies that have submitted the annual certification.

¹ The principles of the Code are derived from a variety of authorities, including the federal Anti-kickback Statute. Throughout the Code, we refer to the concept of an "unlawful inducement" to reflect Anti-kickback Statute prohibitions.

Companies that are AdvaMed members shall, and Companies that are non-members may, supply contact information for the Company's Compliance Department or an anonymous hotline to facilitate reporting of possible violations of the Code. AdvaMed will publish on its website the contact information supplied by each such Company.

Companies are strongly encouraged to follow the seven elements of an effective compliance program, appropriately tailored for each Company, namely: (1) implementing written policies and procedures; (2) designating a compliance officer and compliance committee; (3) conducting effective training and education; (4) developing effective lines of communication (including an anonymous reporting function); (5) conducting internal monitoring and auditing; (6) enforcing standards through well-publicized disciplinary guidelines; and (7) responding promptly to detected problems and undertaking corrective action.

Note: This Amended and Restated Code supersedes and replaces all previous AdvaMed Codes of Ethics. Companies adopting this Code shall communicate the principles of this Code to their employees, agents, dealers and distributors with the expectation that they will adhere to this Code. All Companies have an independent obligation to ensure that their interactions with Health Care Professionals comply with all applicable laws and regulations. The information provided by the Department of Health and Human Services, Office of Inspector General ("OIG"), as well as applicable laws or regulations, may provide more specificity than this Code, and Companies should address any additional questions to their own attorneys. This Code of Ethics is intended to facilitate ethical behavior, and is not intended to be, nor should it be, construed as legal advice. The Code is not intended to define or create legal rights, standards or obligations. Any interpretation of the provisions of this Code, as well as Companies' interactions with Health Care Professionals not specifically addressed in this Code, should be made in light of the following principle: Companies shall encourage ethical business practices and socially responsible industry conduct and shall not engage in any unlawful inducement.

III. Company-Conducted Product Training and Education

Companies have a responsibility to make training and education on their products and Medical Technologies available to Health Care Professionals. Companies may also provide education to Health Care Professionals. "Training" means training on the safe and effective use of Medical Technologies. "Education" means communicating information directly concerning or associated with the use of Companies' Medical Technologies, e.g., information about disease states and the benefits of Medical Technologies to certain patient populations. Training and Education programs include, but are not limited to, "hands on" training sessions, cadaver workshops, lectures and presentations, and grand rounds. In fact, the U.S. Food and Drug Administration mandates training and education to facilitate the safe and effective use of certain Medical Technologies. Companies should adhere to the following principles when conducting training and education programs concerning Medical Technologies for Health Care Professionals:

- Programs and events should be conducted in settings that are conducive to the effective transmission of information. These may include clinical, educational, conference, or other settings, such as hotels or other commercially available meeting facilities. In some cases, it may be appropriate for a Company representative to provide training and education at the Health Care Professional's location.
- Programs providing "hands on" training on Medical Technologies should be held at training facilities, medical institutions, laboratories, or other appropriate facilities. The training staff used by the Company should have the proper qualifications and expertise to conduct such training. Training staff may include qualified field sales employees who have the technical expertise necessary to perform the training.
- Companies may provide Health Care Professional attendees with modest meals and refreshments in connection with these programs. Any such meals and refreshments should be modest in value and subordinate in time and focus to the training and/or educational purpose of the meeting.
- Where there are objective reasons to support the need for out-of-town travel to efficiently deliver Training and Education on Medical Technologies, Companies may pay for reasonable travel and modest lodging costs of the attending Health Care Professionals. It is not appropriate for Companies to pay for the meals, refreshments, travel, or other expenses for guests of Health Care Professionals or for any other person who does not have a *bona fide* professional interest in the information being shared at the meeting.

IV. Supporting Third-Party Educational Conferences

Bona fide independent, educational, scientific, and policymaking conferences promote scientific knowledge, medical advancement and the delivery of effective health care. These typically include conferences sponsored by national, regional, or specialty medical associations and conferences sponsored by accredited continuing medical education providers. Companies may support these conferences in various ways:

- *Conference Grants.* Companies may provide a grant to the conference sponsor to reduce conference costs. They may also provide grants to a training institution or the conference sponsor to allow attendance by medical students, residents, fellows, and others who are Health Care Professionals in training. Companies may provide grants when: (1) the gathering is primarily dedicated to promoting objective scientific and educational activities and discourse; and (2) the training institution or the conference sponsor selects the attending Health Care Professionals who are in training. Such grants should be paid only to organizations with a genuine educational function and may be used to reimburse only the legitimate expenses for *bona fide* educational activities. Such grants also should be consistent with applicable standards established by the conference sponsor and any body accrediting the educational activity. The conference sponsor should independently control and be responsible for the selection of program content, faculty, educational methods, and materials.

Companies may conduct sales, promotional, and other business meetings with Health Care Professionals to discuss, for example, Medical Technology features, sales terms, or contracts. Often, these meetings occur close to the Health Care Professional's place of business. It is appropriate to pay for reasonable travel costs of attendees when necessary (e.g., for plant tours or demonstrations of non-portable equipment) and/or to provide occasional modest meals and refreshments in connection with such meetings. However, it is not appropriate to pay for meals, refreshments, travel, or lodging of guests of Health Care Professionals or any other person who does not have a *bona fide* professional interest in the information being shared at the meeting. See Section VIII for additional principles related to the provision of meals associated with Health Care Professional business interactions.

Companies engage Health Care Professionals to provide a wide-range of valuable, *bona fide* consulting services through various types of arrangements, such as contracts for research, product development, development and/or transfer of intellectual property, marketing, participation on advisory boards, presentations at Company-sponsored training and other services. Companies may pay consultants fair market value compensation for performing these types of services, provided that they are intended to fulfill a legitimate business need and do not constitute an unlawful inducement. Companies should comply with the following standards in connection with consulting arrangements with Health Care Professionals:

- Revised and Restated Code of Ethics**
Effective July 1, 2009

- Consulting arrangements should be entered into only where a legitimate need for the services is identified in advance and documented.
- Selection of a consultant should be made on the basis of the consultant's qualifications and expertise to meet the defined need.
- Compensation paid to a consultant should be consistent with fair market value in an arm's length transaction for the services provided and should not be based on the volume or value of the consultant's past, present or anticipated business.
- A Company may pay for documented, reasonable and actual expenses incurred by a consultant that are necessary to carry out the consulting arrangement, such as costs for travel, modest meals, and lodging.
- The venue and circumstances for Company meetings with consultants should be appropriate to the subject matter of the consultation. These meetings should be conducted in clinical, educational, conference, or other settings, including hotel or other commercially available meeting facilities, conducive to the effective exchange of information.
- Company-sponsored meals and refreshments provided in conjunction with a consultant meeting should be modest in value and should be subordinate in time and focus to the primary purpose of the meeting. Companies should not provide recreation or entertainment in conjunction with these meetings.
- A Company's sales personnel may provide input about the suitability of a proposed consultant, but sales personnel should not control or unduly influence the decision to engage a particular Health Care Professional as a consultant. Companies should consider implementing appropriate procedures to monitor compliance with this section.

Provisions on Payment of Royalties. Arrangements involving the payment of royalties to a Health Care Professional should meet the contractual standards set forth above. Health Care Professionals, acting individually or as part of a group in which they are an active participant, often make valuable contributions that improve products or Medical Technologies. They may develop intellectual property, for example, patents, trade secrets, or know-how, under a product or technology development or intellectual property licensing agreement. A Company should enter into a royalty arrangement with a Health Care Professional only where the Health Care Professional is expected to make or has made a novel, significant, or innovative contribution to, for example, the development of a product, technology, process, or method. A significant contribution by an individual or group, if it is the basis for compensation, should be appropriately documented.

The calculation of royalties payable to a Health Care Professional in exchange for Intellectual Property should be based on factors that preserve the objectivity of medical decision-making and avoid the potential for improper influence. For example, royalties paid in exchange for Intellectual Property should not be conditioned on: (1) a requirement that the Health Care Professional purchase, order or recommend any product or medical technology of the

Other principles. Depending on the type of business interaction or meeting, additional principles may apply, as described in other sections of this Code of Ethics. Specifically:

- **Section III: Company-Conducted Product Training and Education.**
- **Section IV: Supporting Third-Party Educational Conferences.**
- **Section V: Sales, Promotional, and Other Business Meetings.**
- **Section VI: Consulting Arrangements with Health Care Professionals.**

IX. Educational Items; Prohibition on Gifts

A Company occasionally may provide items to Health Care Professionals that benefit patients or serve a genuine educational function for Health Care Professionals. Other than medical textbooks or anatomical models used for educational purposes, any such item should have a fair market value of less than \$100. A Company may not provide items that are capable of use by the Health Care Professional (or his or her family members, office staff or friends) for non-educational or non-patient-related purposes, for example, a DVD player or MP3 player/i-Pod.

A Company may not give Health Care Professionals any type of non-educational branded promotional items, even if the item is of minimal value and related to the Health Care Professional's work or for the benefit of patients. Examples of non-educational branded promotional items include pens, notepads, mugs, and other items that have a Company's name, logo, or the name or logo of one of its Medical Technologies. Companies also may not provide Health Care Professionals with gifts such as cookies, wine, flowers, chocolates, gift baskets, holiday gifts or cash or cash equivalents.

This section is not intended to address the legitimate practice of providing products for evaluation and demonstration purposes, which is addressed in Section XII.

X. Provision of Coverage, Reimbursement and Health Economics Information

As Medical Technologies have become increasingly complex, so have payor coverage and reimbursement policies. Patient access to necessary Medical Technology may be dependent on Health Care Professionals and/or patients having timely and complete coverage, reimbursement, and health economic information. Consequently, a Company may provide such information regarding its Medical Technologies if it is accurate and objective. A Company also may collaborate with Health Care Professionals, patients and organizations representing their interests, to achieve government and commercial payor coverage decisions, guidelines, policies, and adequate reimbursement levels that allow patients to access its Medical Technologies.

Permissible activities involving the provision of coverage, reimbursement and health economic information may include, but are not limited to:

- Identifying the clinical value of the Company's Medical Technologies and the services and procedures in which they are used when providing coverage, reimbursement and health economics information and materials to Health Care Professionals, professional organizations, patient organizations, and payors.
- Collaborating with Health Care Professionals, their professional organizations, and patient groups to conduct joint advocacy on coverage, reimbursement and health economics issues; supporting Health Care Professionals and their professional organizations in developing materials and otherwise providing direct or indirect input into payor coverage and reimbursement policies.
- Promoting accurate Medicare and other payor claims by providing accurate and objective information and materials to Health Care Professionals regarding the Company's Medical Technologies, including identifying coverage, codes and billing options that may apply to those Medical Technologies or the services and procedures in which they are used.
- Providing accurate and objective information about the economically efficient use of the Company's Medical Technologies, including where and how they can be used within the continuum of care.
- Providing information related to the Company's Medical Technologies regarding available reimbursement revenues and associated costs.
- Providing information relating to changes in coverage or reimbursement amounts, methodologies and policies and the effects of such changes in order to facilitate a Health Care Professional's decision to buy or use the Company's Medical Technologies.
- Providing accurate and objective information designed to offer technical or other support intended to aid in the appropriate and efficient use or installation of the Company's Medical Technologies.
- Facilitating patient access to the Company's Medical Technologies by providing Health Care Professionals with assistance in obtaining patient coverage decisions from payors. This assistance may include providing information and/or training on payor policies and procedures for obtaining prior authorization, and providing sample letters and information on medical necessity and appeals of denied claims. In addition, at the request of a Health Care Professional to facilitate patient access to the Company's Medical Technology, and subject to appropriate privacy safeguards, the Company may assist the patient by facilitating the preparation and submission of requests for coverage determinations, prior authorizations, pre-certifications and appeals of denied claims, relating to a Company's own Medical Technology; however such assistance should not be provided as an unlawful inducement.

A Company may not interfere with a Health Care Professional's independent clinical decision-

making or provide coverage, reimbursement and health economics support as an unlawful inducement. For example, a Company should not provide free services that eliminate an overhead or other expense that a Health Care Professional would otherwise of business prudence or necessity have incurred as part of its business operations if doing so would amount to an unlawful inducement. Further, a Company should not suggest mechanisms for billing for services that are not medically necessary, or for engaging in fraudulent practices to achieve inappropriate payment.

XI. Research and Educational Grants and Charitable Donations

A Company may provide research and educational grants and charitable donations. However, a Company may not provide such grants or donations as an unlawful inducement. Therefore, a Company should: (a) adopt objective criteria for providing such grants and donations that do not take into account the volume or value of purchases made by, or anticipated from, the recipient; (b) implement appropriate procedures to ensure that such grants and donations are not used as an unlawful inducement; and (c) ensure that all such grants and donations are appropriately documented. A Company's sales personnel may provide input about the suitability of a proposed grant or charitable donation recipient or program, but sales personnel should not control or unduly influence the decision of whether a particular Health Care Professional or institution will receive a grant or donation or the amount of such grant or donation. Companies should consider implementing procedures to monitor compliance with this section.

a. Research Grants

Research provides valuable scientific and clinical information, improves clinical care, leads to promising new treatments, promotes improved delivery of health care, and otherwise benefits patients. In furtherance of these objectives, a Company may provide research grants to support independent medical research with scientific merit. Such activities should have well-defined objectives and milestones and may not be linked directly or indirectly to the purchase of Medical Technologies.

Company-initiated or directed research involving a Company's Medical Technologies (such as clinical study agreements) is addressed separately in Section VI.

b. Educational Grants

Educational grants may be provided for legitimate purposes, including, but not limited to, the examples below. As noted in Section IV, a Company may make educational grants to conference sponsors or training institutions. A Company may not make educational grants to individual Health Care Professionals.

- *Advancement of Medical Education.* A Company may make grants to support the genuine medical education of medical students, residents, and fellows participating in fellowship programs that are charitable or have an academic affiliation, or other medical personnel. (For additional considerations regarding educational grants, see Section IV.)
- *Public Education.* A Company may make grants for the purpose of supporting education

of patients or the public about important health care topics.

c. Charitable Donations

A Company may make monetary or Medical Technology donations for charitable purposes, such as supporting indigent care, patient education, public education, or the sponsorship of events where the proceeds are intended for charitable purposes. Donations should be motivated by *bona fide* charitable purposes and should be made only to *bona fide* charitable organizations or, in rare instances, to individuals engaged in genuine charitable activities for the support of a *bona fide* charitable mission. Companies should exercise diligence to ensure the *bona fide* nature of the charitable organization or charitable mission.

XII. Evaluation and Demonstration Products

Providing products to Health Care Professionals at no charge for evaluation or demonstration purposes can benefit patients in many ways. These benefits include improving patient care, facilitating the safe and effective use of products, improving patient awareness, and educating Health Care Professional regarding the use of products. Under certain circumstances described below, a Company may provide reasonable quantities of products to Health Care Professionals at no charge for evaluation and demonstration purposes.

This section is limited to providing evaluation and demonstration products only and is not intended to address any other arrangement.

Company products that may be provided to Health Care Professionals for evaluation include single use (e.g., consumable or disposable products) and multiple use products (sometimes referred to as "capital equipment"). These products may be provided at no charge to allow Health Care Professionals to assess the appropriate use and functionality of the product and determine whether and when to use, order, purchase, or recommend the product in the future. Company products provided for evaluation are typically expected to be used in patient care.

Single Use/Consumables/Disposables. The number of single use products provided at no charge should not exceed the amount reasonably necessary for the adequate evaluation of the products under the circumstances.

Multiple Use/Capital. Multiple use products provided without transfer of title for evaluation purposes should be furnished only for a period of time that is reasonable under the circumstances to allow an adequate evaluation. The terms of an evaluation of such multiple use products should be set in advance in writing. Companies should retain title to such multiple use products during the evaluation period and should have a process in place for promptly removing such multiple use products from the Health Care Professional's location at the conclusion of the evaluation period unless the Health Care Professional purchases or leases the products.

Demonstration. Company demonstration products are typically unsterilized single use products or mock-ups of such products that are used for Health Care Professional and patient awareness, education, and training. For example, a Health Care Professional may use a demonstration product to show a patient the type of device that will be implanted in the patient. Demonstration

products typically are not intended to be used in patient care. Demonstration products also are typically identified as not intended for patient use by use of such designations as "Sample," "Not for Human Use," or other suitable designation on the product, the product packaging, and/or documentation that accompanies the product.

A Company should provide Health Care Professionals with documentation and disclosure regarding the no-charge status of evaluation and demonstration products.

FREQUENTLY ASKED QUESTIONS

REGARDING ADVAMED'S CODE OF ETHICS ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS

SECTION I: PREAMBLE AND GENERAL QUESTIONS

Q1 Why did AdvaMed develop a code distinct from the PhRMA Code on Interactions with Health Care Professionals?

The AdvaMed Code of Ethics is intended to address the unique interactions that occur between Companies and Health Care Professionals, just as the PhRMA Code reflects the nature of interactions between pharmaceutical companies and Health Care Professionals. Distinguishing features in AdvaMed's Code arise primarily from the fact that Companies interact with Health Care Professionals because of the complexity and "hands on" nature of Medical Technologies and the importance of having Health Care Professionals understand how to use the technologies safely and effectively.

Q2 Who are "Health Care Professionals"? Does the term include non-clinical people who make Medical Technology purchasing decisions? Does it include decision-makers within GPOs?

The phrase "Health Care Professionals" is intended to be a broad one. It includes individuals or entities: 1) which are involved in the provision of health care services and/or items to patients; and 2) which purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Companies' Medical Technologies in the United States. The phrase Health Care Professional includes both persons providing services (such as licensed physicians) and persons who do not provide services directly but who are involved in the decision to purchase, lease, or recommend a Medical Technology. These individuals include, for example, purchasing agents, physician's practice managers and management within group purchasing organizations ("GPOs").

Q3 Does the Code apply to gifts, meals, refreshments, and other benefits provided by Companies to government employees?

Yes, the Code applies to gifts, meals, refreshments, and other benefits provided by Companies to government employees if the employees are Health Care Professionals. Companies also should be aware that there may be specific legal restrictions on providing gifts and other benefits to government employees, and that these restrictions may, in some cases, be more restrictive than the Code.

Q4 Does the Code cover interactions with Health Care Professionals whose primary place of work is outside the U.S.? Does it cover interactions outside the U.S. with Health Care Professionals who work in the U.S.?

The Code applies to interactions with Health Care Professionals to the extent that they provide services or Medical Technologies in the United States. This would include interactions with Health Care Professionals who work in the United States, even if the interaction occurs outside

Yes, interactions related to combination products (e.g., those that are both biologics and devices or drugs and devices) are covered by the Code. Interactions related to combination products also may be subject to the ethical codes of other trade associations.

If these arrangements involve providing services to a Company, they are a type of consulting arrangement addressed in Section VI.

**“Modest” means moderate value, but may differ depending on regional differences.
“Occasional” means infrequent.**

Q8 May a Company's employee or agent pay for meals or refreshments for a Health Care Professional that a Company could not provide under the Code, if the Company neither pays for the meals or refreshments nor reimburses the employee or agent?

Q9 May a Company offer to provide laptop computers with independent value to any purchasing manager whose hospital purchases at least 1,000 units of the Company's medical technology that the Company has just introduced?

Q10 May a Company provide support for a Health Care Professional-sponsored social event, such as an office holiday party?

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SECTION II: CODE OF ETHICS COMPLIANCE

Q11 What form should Companies use to make the certification described in Section II, and on what date are such certifications due?

The revised AdvaMed Code of Ethics will take effect on July 1, 2009. Company certifications should be submitted no later than July 1 of each year, beginning in 2010. AdvaMed will publish the certification form that Companies should use. While it may take a period of time for Companies to adopt the revised Code, create and implement policies, procedures and effective compliance programs to comply with the Code, and educate and train employees whose job responsibilities make the information relevant, Companies should endeavor to accomplish these tasks as diligently as reasonably possible.

Q12 Does the AdvaMed Code of Ethics offer legal advice?

No. The Code is intended to facilitate ethical behavior and is not intended to be, nor should it be, construed as legal advice. All Companies have an independent obligation to ensure that their interactions with Health Care Professionals comply with all applicable laws and regulations.

Q13 Will AdvaMed staff provide advice on how the Code would apply to specific practices?

No. Companies should address questions about specific practices to their own attorneys or advisors.

Q14 Does the Code govern the actions of Companies' agents and distributors?

As stated in Section II, Companies adopting the Code are required to communicate the Code's provisions to their employees, agents, dealers and distributors with the expectation that they will adhere to them. It is important that these entities are informed that AdvaMed has revised its Code of Ethics and that they are aware of the ethical standards reflected in it.

Q15 What does "appropriately tailored" mean with respect to implementation of the seven elements of an effective compliance program?

"Appropriately tailored" means that each Company's implementation of the seven elements of an effective compliance program should take into account the Company's size, resources, particular lines of business, and work-force. AdvaMed recognizes that, given the wide diversity within the medical technology industry, there is no single best compliance program. AdvaMed strongly encourages Companies to develop and implement compliance elements that address the specific types of risks that apply to their operations.

SECTION III: COMPANY-CONDUCTED PRODUCT TRAINING AND EDUCATION

Q16 Why may it be appropriate under the Code for Companies to pay for travel to attend training and education sessions?

In order to efficiently deliver training and/or education at appropriate facilities, the Code contemplates that a Company may bring Health Care Professionals together at a central location, which may make out-of-town travel necessary. Note that this section deals only with meetings focused on training and education on Medical Technologies, and only for persons who could legitimately benefit from the training and education. (Meetings focused on sales, promotional, and other business meetings are discussed in Section V.)

Q17 May a Company pay for travel to a Company-sponsored general educational program (not related to a Medical Technology)?

It may be appropriate for a Company to conduct a general educational session, but it is not the type of program for which Company-supported travel would be appropriate under the Code. In contrast, paying for a Health Care Professional's travel may be appropriate when the Company is conducting training and education on the safe and effective use of its Medical Technologies.

SECTION IV: SUPPORTING THIRD-PARTY EDUCATIONAL CONFERENCES

Q18 May a Company designate attendees or faculty who will speak at a third-party educational conference?

No. The Code contemplates that an independent third party will select faculty and attendees. The Code does not preclude a Company from recommending a knowledgeable faculty member, where the recommendation is permitted by the conference sponsor's guidelines. The ultimate selection should be made by the conference sponsor.

Q19 May a Company provide an educational grant to support the attendance of a Health Care Professional at a third-party educational conference?

The Code contemplates that grants would be made to the conference sponsor or training institution, which will select the attendees. Furthermore, the Code contemplates that the benefited attendees would be medical students, residents, fellows, or other Health Care Professionals in training.

Q20 If a Company provides a grant for a medical student to attend an educational conference, may the funds be used to cover both travel expenses and registration fees?

Yes, provided that the grant is given directly to a training institution or a third party educational conference sponsor.

SECTION V: SALES, PROMOTIONAL, AND OTHER BUSINESS MEETINGS

AdvaMed's Code of Ethics is mindful of the desire to avoid even the appearance that business courtesies are being given as improper inducements to promote a Company's Medical Technologies. On the other hand, Companies may, as a matter of common courtesy and civility, provide occasional modest meals or refreshments for Health Care Professionals in connection with these types of meetings that are conducive to the exchange of information. The Code precludes the extension of these courtesies to persons, such as guests/spouses, without a *bona fide* professional interest in the meeting.

Generally, this would not be appropriate. Companies should be deliberate in selecting the location and venue for such meetings. Like location and venue selection for training and education meetings (discussed in Section III), Companies should select a location and venue that is appropriate for, and conducive to, accomplishing the purpose of the meeting. Selection of a resort location would not likely meet these standards and may give rise to an appearance of impropriety. In addition, the location should be evaluated for consistency with the provisions in Section V, which state that it may be appropriate at sales, promotional, or other business meetings to provide occasional modest meals or refreshments and, with respect to providing travel, that the travel be "necessary." Furthermore, the Code provides for limited special circumstances of "plant tours and demonstrations of non-portable equipment" as specific examples of when travel might be necessary.

No. Companies should always promote adherence to the Code by intermediaries when they are engaged in marketing the Company's Medical Technologies. A Company should never knowingly encourage or condone an intermediary's engaging in conduct that would be prohibited by the Code if a Company engaged in it directly.

SECTION VI: CONSULTING ARRANGEMENTS WITH HEALTH CARE PROFESSIONALS

Q25 Is a clinical investigator considered a “consultant” under Section VI?

If the clinical investigator is providing services to the Company in return for compensation, he or she is a consultant under Section VI.

Q26 Is there a limit to the number of consultants a Company may retain under Section VI?

Companies may retain only as many consultants as are necessary to fulfill the Company’s requirements for *bona fide* services; moreover, the requirements of Section VI must be satisfied for each consultant.

Q27 May a consultant be placed under retainer with services provided as requested?

Yes, provided the requirements of Section VI are met.

Q28 What happens if a consultant is engaged but the project is cancelled or modified without using the consultant’s services?

The Code contemplates that if the requirements of Section VI were met when the consultant was engaged and then unanticipated circumstances prevented performance, then the question of whether or how much payment is made to a consultant would be a matter determined by the underlying consulting agreement. However, any such payment should be reasonable under the circumstances.

Q29 What factors should a Company consider when evaluating the venues and circumstances for meetings with consultants?

A Company should assess (a) whether there is a *bona fide* business justification for holding the meeting; (b) whether the location and venue are suitable for and conducive to the exchange of information; (c) whether the value of any Company-sponsored lodging is reasonable; (d) whether any ancillary meals and refreshments are modest in value and are subordinate in time and focus to the business part of the meeting; and (e) whether the overall meeting has a genuine business purpose and tenor and does not constitute an unlawful inducement.

Q30 Do the restrictions of the AdvaMed Code apply to Company interactions with consultants in the same way as they do to interactions with other Health Care Professionals?

Yes. All interactions with Health Care Professionals must meet the requirements of the Code. These include the requirements of Section VI as well as other applicable sections of the Code.

Q31 When is a Health Care Professional considered a “consultant”? What types of arrangements with consultants are covered under Section VI?

Section VI provides that a consultant should be selected on the basis of his or her qualifications and expertise to meet a defined need. It is possible that these qualifications could include experience with, usage of, or familiarity with a specific Medical Technology. However, neither selection of, nor compensation paid to, consultants should be to reward past usage or constitute an unlawful inducement.

Arrangements that involve the provision of clinical research services by a Health Care Professional in return for compensation are a type of consulting arrangement and are subject to the same principles as other consulting arrangements under the Code. They should be governed by a written services agreement, and compensation should be based on fair market value for the services provided. The clinical program for which the services are being provided should fulfill a legitimate research purpose.

Q34 How can a Company establish "fair market value"?

There are different valuation methods that may be used to establish fair market value. In all instances, a Company should use objective, verifiable criteria. The method or methods used by a Company should be documented.

A legitimate need arises when a Company requires the services of a Health Care Professional in order to achieve a proper business objective. There are many proper business objectives. However, engaging a Health Care Professional for the purpose of generating business directly

Q36 May a Company's employee or agent pay for entertainment or recreation for a Health Care Professional that a Company could not provide under the Code, if the Company neither pays for the entertainment or recreation nor reimburses the employee or agent?

SECTION VIII: MODEST MEALS ASSOCIATED WITH HEALTH CARE PROFESSIONAL BUSINESS INTERACTIONS

No. A business presentation may include substantial discussions related to medical technology development and improvement of a medical technology, pricing, or contract negotiations. The business discussion should account for most of the time spent during the meal. Development of general goodwill and business relationships should not be the primary purpose of a business meal, and a business meal should not be used for entertainment or recreational purposes.

Q38 May a Company provide a gift such as flowers, gift baskets, meals, snacks, wine, or other refreshments to a Health Care Professional or a Health Care Professional's office or staff?

Q39 May a Company give gifts to staff of a Health Care Professional who are not themselves Health Care Professionals?

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Q40 May a Company or its representative provide a gift to recognize a life event for a Health Care Professional, such as a wedding, birth, anniversary, or death of a family member?

No. A Company, or representative acting on the Company's behalf, may only provide items to Health Care Professionals that are intended for the benefit of patients or serve a genuine educational function for the Health Care Professional. Gifts such as flowers, fruit baskets, etc. do not meet this requirement even if provided to recognize a significant life event.

Q41 May a Company raffle an item during a trade show, such as two round-trip airline tickets, that it could not otherwise give as a gift?

No. A Company may not raffle or give away at a trade show an item that it could not otherwise give a Health Care Professional under Section IX.

Q42 What types of items are considered to be for the benefit of patients?

Items intended for the benefit of patients could include starter kits, and educational brochures, for example. However, "scrubs" and office supplies would not be considered an item for the benefit of patients. With respect to starter kits, a Company should adopt appropriate safeguards regarding the provision of such kits to ensure they are not offered as an unlawful inducement.

SECTION X: PROVISION OF COVERAGE, REIMBURSEMENT, AND HEALTH ECONOMICS INFORMATION

Q43 Is it appropriate to demonstrate that a Medical Technology can be used in an economically efficient manner?

It may be appropriate for Companies to provide accurate information relating to the costs, savings and revenues associated with the use of its Medical Technologies. Without this information, it may be difficult for a Health Care Professional to properly evaluate their economic feasibility or desirability.

SECTION XI: RESEARCH AND EDUCATIONAL GRANTS AND CHARITABLE DONATIONS

Q44 What is an example of a grant or donation to "individuals engaged in genuine charitable missions for the support of that mission"?

One example is providing medical technologies to individuals who perform volunteer disaster relief abroad. Supporting disaster relief work may be appropriate under the Code, notwithstanding that the individuals or group are acting as independent volunteers and not under the umbrella of a not-for-profit, charitable organization.

Q45 May a Company make a charitable contribution to a not-for-profit institution to pay the registration or seminar fees and travel expenses for an affiliated Health Care Professional to attend a third-party educational conference?

In general, Section IV does not permit a Company to pay directly for the registration, seminar fees or travel expenses of a Health Care Professional's attendance at a third-party educational conference. Consequently, the Company should not provide these benefits indirectly as a charitable contribution to a Health Care Professional's not-for-profit institution for the purpose of defraying the costs of particular individuals' attendance. However, it can provide grants to sponsors to: 1) pay the expenses of faculty members selected by the conference sponsor; 2) support the participation of Health Care Professionals in training; or 3) reduce the costs of participation by all participants.

Q46 May a Company make a charitable contribution to a not-for-profit hospital for construction of a new wing?

Companies have historically supported the delivery of health care services through charitable contributions. As with any other contribution, this type of contribution may be appropriate if: (a) the recipient of the contribution is a charitable organization; (b) the purpose of the donation is charitable in nature; and (c) it is not an unlawful inducement. Many factors would be involved in considering whether such a contribution is appropriate, including ensuring that the amount of the donation is not dependent upon the volume of business or anticipated business conducted with or referred to the Company.

Q47 May a Company make an educational grant to pay for a clinical fellow?

A Company may make an educational grant to an institution to subsidize a clinical fellow if the fellow is in a genuine fellowship program which has a charitable or academic affiliation. A Company may not use the provision of an educational grant as an unlawful inducement.

Q48 May a Company pay for or provide tickets to a Health Care Professional or spouse or guest to attend charitable events, such as galas and golf outings?

No. A Company may not pay for or provide tickets to Health Care Professionals or their spouses or guests to attend charitable events, such as galas and golf outings.

Q49 May a Company give a Health Care Professional a research grant that is unrestricted and can be used for any purpose?

No. A Company should give research grants only if they are in support of research that has defined goals, objectives, and milestones.

Q50 May a Company make a contribution in support of a Health Care Professional's charitable event (e.g., golf tournament, outing, gala dinner, and the like), where the proceeds earned from the event will be used for charitable purposes?

Yes, so long as the donation is not an unlawful inducement. However, a Company may not pay for an individual Health Care Professional to attend or participate in the charitable event.

Q51 How can a Company determine whether a charitable organization is a *bona fide* charitable organization?

Companies should exercise diligence to ensure the charitable organization is *bona fide*. Relevant factors to consider may include (1) the entity's tax status, (2) the entity's corporate status under state law, and (3) whether the organization has a charitable mission or purpose, among other factors.

SECTION XII: EVALUATION AND DEMONSTRATION PRODUCTS

Q52 May a Company provide a recently approved product without charge to a Health Care Professional for evaluation?

Yes, but the Company should provide the Health Care Professional with documentation about the product to allow the Health Care Professional to appropriately address any obligation to report for reimbursement purposes.

Q53 A Health Care Professional has requested that a Company provide it with a multiple use product to evaluate. How long can the Company provide the product at no charge to the Health Care Professional?

The specific length of time reasonably necessary for a Health Care Professional to assess a multiple use product will depend on the frequency of anticipated use, the duration of required training, the number of Health Care Professionals who will need to evaluate the product, the length of time necessary to evaluate different product features, and similar considerations. A Company should provide a Health Care Professionals with documentation and disclosure regarding the no-charge status of evaluation products.

Q54 Is a demonstration or evaluation product that is provided at no charge to a Health Care Professional by a Company a gift?

No. Demonstration and evaluation products are not considered gifts under Section IX.

<input type="checkbox"/> 426.7	Walden-Parkinson-Witzke Disease	<input type="checkbox"/> ENK	
<input type="checkbox"/> V72.81	Pre Op Cardiovascular	<input type="checkbox"/> Blood Pressure Check	
<input type="checkbox"/> V45.82	S/P Stent	<input type="checkbox"/> ICG	
<input type="checkbox"/> 423.9	Pericardial Effusion	<input type="checkbox"/> Lipid Clinic	
<input type="checkbox"/> 420.90	Pericarditis	<input type="checkbox"/> Cardiac Rehab	
<input type="checkbox"/> 745.5	Atrial Septal Defect	<input type="checkbox"/> Counseling Clinic	
		<input type="checkbox"/> ECP	

EXHIBIT 5

DATE		TIME		PATIENT		REASON				PRIOR BALANCE											
02/17/01		[REDACTED]		[REDACTED]		3RD/PACER CK				PAT 264.16 INS 116.00 1.											
CKET NO.		DR.#		DOCTOR		LOCATION		D.O.B.		TODAY'S CHARGE											
[REDACTED]		12		PACER		BRADENTON HEART CENT		[REDACTED]		3.											
PATIENT NO.		RESPONSIBLE PARTY		PHYSICIAN		REFERRING DR.				4.											
[REDACTED]		[REDACTED]		[REDACTED]		[REDACTED]				ADJUSTMENTS											
M		F		ADDRESS		CITY/STATE		ZIP CODE		6.											
[REDACTED]		[REDACTED]		BRADENTON		FL		34205		7.											
CAP		OVER 90		OVER 60		OVER 30		CURRENT		TOTAL DUE		PT		BC		CS		PAY CHOICE		TODAY'S PAYMENT	
177.00		43.54		21.77		137.77		388.16		38		3		4						9.	
INSURANCE COMPANY				BA		SCT		POLICY I.D.				RELATIONSHIP TO INSURED				BALANCE DUE					
UNITED HEALTHCARE AT Y				[REDACTED]		[REDACTED]		[REDACTED]				SELF				CHILD					
SSN # [REDACTED]				[REDACTED]		[REDACTED]		414.01 CAD-NATIVE VESSEL				OTHER									

Medications	Date	Size	Frequency	Count
ASA	060704	81MG	QD	KH
ALTACE	110304	10MG	QD	NP
AMIODARONE	110304	200MG	QD	NP
LASIX	110304	40MG	BID	NP
KCL	110304	20KED	BID	NP
DARVOCET	110304	N-100	PRN	NP
MTSC/RED	110304	CYMBALT	30MG AS	NP
TOPROL XL	111604	200MG	QD	NP
ZOCOR	111604	20MG	QD	NP
HWT	022505		QD	LM

I hereby authorize my insurance benefits to be paid directly to the above signed physician, realizing I am responsible to pay non-covered services and hereby authorize the release of pertinent medical information to insurance carriers.

Patient Signature _____

Suite 4200
 L 34209
 99
 2-4048
 711

DIAGNOSIS	CODE	DIAGNOSIS	CODE	DIAGNOSIS	CODE	DIAGNOSIS	NEXT APPT.	WHEN
✓ BLK I	785.9	Carotid Bruit	272.0	Hypercholesterolemia	✓ V45.02	S/P ICD	✓ OV	
✓ BLK II	433.10	Carotid Occlusion	272.4	Hyperlipidemia	✓ V45.01	S/P Pacemaker	✓ Test Results	
am Aortic Aneurysm	433.11	Cerebrovascular Disease	401.9	Hypertension	✓ V45.82	S/P Stent	✓ Spect Myoview	
armal EKG	786.50	Chest Pain	458.9	Hypotension	✓ 451.0	Superficial Veins	✓ Persantine Myoview	
armal Function Study	428.32	Chronic Diastolic Heart Failure	396.9	Mitral/Aortic Valve Dis.		Thrombophlebitis	✓ Rest/Stress RNA	
armal Diastolic Heart Failure	416.9	Chronic Pulmonary Heart Dis.	394.0	Mitral Stenosis	✓ 780.2	Syncope	✓ Adenosine Myoview	
armal on Chronic Diastolic Heart Failure	428.22	Chronic Systolic Heart Failure	424.0	Mitral Valve Disorder	✓ 427.0	Tachycardia, Paroxysmal	✓ Dobutamine Stress	
armal te on Chronic Systolic Heart Failure	428.0	Congestive Heart Failure	412	Old MI		Supra Vent.	✓ Muga Scan	
armal te on Chronic Systolic Heart Failure	496	COPD	780.79	Other Malaise + Fatigue	✓ 427.1	Tachycardia, Ventricular, Paroxysmal	✓ Regular Stress	
armal na Pectoris	414.06	Coronary Atherosclerosis of Coronary Artery of Transp. Heart	785.1	Palpitations	✓ 427.41	Tachycardia, Vent. FIB	✓ Echo w/Color/Doppler	
armal tic Stenosis Rheumatic	790.92	Coumadin Therapy	423.9	Pericardial Effusion	✓ 427.42	Tachycardia, Vent. Flutter	✓ Echo Limited	
armal tic Valve Disorder	395.9	Diseases of Aortic Valve	420.90	Pericarditis	✓ 414.9	Transient Cardiac Ischemia	✓ T-wave	
armal rhythmia/Cardiac Dysrhythmia	394.9	Diseases of Mitral Valve	443.9	Peripheral Vascular Disease	✓ 435.9	Transient Cerebral Ischemia	✓ Stress Echo	
armal erosci. Lwr Ext Art	414.12	Dissection of Coronary Artery	✓ V72.61	Pre Op Cardiovascular	✓ 397.0	Tric. Insul. Rheumatic	✓ Carotid Duplex	
armal al Fibrillation	780.4	Dizziness	425.4	Primary Cardiomyopathy	✓ 424.2	Tricuspid Insul.	✓ Lower Arterial w/PVR	
armal al Flutter	250.00	DM-Adult Onset	415.19	Pulmonary Embolism	✓ 428.20	Unsp. Systolic Heart Failure	✓ Lower Arterial Duplex	
armal al Septal Defect	250.01	DM-Insulin Dependent	416.0	Pulmonary HTN-Primary	✓ 411.1	Unstable Angina	✓ Lower Venous	
armal overventricular Block-Complete	451.11	DVT Femoral Vein	416.8	Pulmonary HTN-Secondary	✓ 444.21	Upper Extremity Occlusion	✓ Renal Duplex	
armal ign HYP HRT	451.19	DVT Pop. Tibial	442.3	Pseudoaneurysm	✓ V43.3	Valve Replacement	✓ Aorta	
armal edycardia	782.3	Edema	398.90	Rheumatic Heart Disease	✓ 454	Varicose Veins Lwr Ext	✓ Hoffer	
armal D, Auto Bypass	276.6	Fluid Retention	786.05	Shortness of Breath		Specify	✓ Pacer Check	
armal D, Native	785.2	Heart Murmur	427.81	Sinoatrial Node Dysfunction SSS	✓ 593.81	Vascular Disorder of Kidney, Renal Artery Thrombosis	✓ ICD Check	
armal D, unsp			451.81	S/P CABG/Bypass			✓ EKG	
							✓ Blood Pressure Check	

OFFICE VISITS	FEE	✓	CODE	NONINVASIVE PROCEDURES	FEE
			80390	Therapeutic Injection	

NEW	GR	TEST	AB	SHED	
					90762 Theophylline Intoxication
Level I		99211	Level I		78481 Rest RNA/First Pass
Level II		99212	Level II		93015 Exercise Stress Test
Level III		99213	Level III		78478 Myocardial Perfusion
Level IV		99214	Level IV		78465 Tomographic Spect Multiple
Level V		99215	Level V		78480 Perfusion Study w/Elec Frac
					10500 Cardiolite

Post Op Visit	A5500	Marocaine
CONSULTATIONS		
	A9502	Myoview per dose
Level I	J1245	Persantine
Level II	J1250x1	Dobutamine
Level III	J0151	Adenosine
Level IV	J0280	Aminophylline
	WA132x1	MUGA

Level V	DESCRIPTION		
	Lipid Panel	78472	MUGA
	AST-SGOT	93025	Micro-volt T-wave Alternans
	ALT-SGPT	93306	Echocardiogram-Complete
	EKG with Report	93320	Cardiac Doppler
	Signal Avg. EKG	93325	Cardiac Doppler Color Flow
	Rhythm Strip	93321	Cardiac Doppler Limited
	Pacer Evaluation-Single/Dual	93350	Echo w/Exercise (93015)
	Pacer Reprogram-Dual	93308	Echo Limited
	Pacer Reprogram-Single	93701	Bio-Z 1 or 2
	ICD Eval & Report-Single/Dual	93880	Carotid Imaging, Real Time
	ICD Single Reprogram	93922	Lwr Art BP-ABJ
	ICD Dual Reprogram	93923	Up/Lwr Art BP, PVR/Resl
	Elec. Analysis Implantable Loop Records	93924	Up/Lwr Art BP, PVR/Exercise
	Hook up Loop Monitor	93925	Lower Arterial Imaging
	Interp Loop Monitor	93926	Limited Arterial Imaging
	Interp Non Loop Monitor	93930	Upper Arterial Imaging
	Holter Monitor Global	93965	Lower Ext Venous CW, PPG
	Venipuncture	93970	Lower Venous Imaging
	Protime	93971	Upper Venous Imaging
	IV Lasix 20mg	93975	Renal Duplex
	IV Digoxin	93978	Aorta-Iliac Ultrasound
	Atropine	93784	24" BP Monitor
		J7051	Saline 5cc
		G0165	ECP
		93979	CELIAC Ultrasound

<input type="checkbox"/>	459.81	Venous Insuff.	<input type="checkbox"/>	ICG
<input type="checkbox"/>	453.8	Venous Thrombosis Upper Ext	<input type="checkbox"/>	Lipid Clinic
<input type="checkbox"/>	796.2	White Coat Hypertension	<input type="checkbox"/>	Cardiac Rehab
<input type="checkbox"/>	426.7	Wolff-Parkinson-White Disease	<input type="checkbox"/>	Obumadin Clinic
			<input type="checkbox"/>	CPB

PATIENT INFORMATION

This image shows a blank ledger page. On the left side, there is a vertical column consisting of 20 small, empty squares, likely for recording numerical data. The rest of the page is a large, empty rectangular area, typically used for writing descriptive text or providing details for each entry.

TIME	PATIENT	REASON	PAT	PRIOR BALANCE
8/18 1.30	██████████	2WK F/UP +PACER CK	INS	0.00
				2976.00

NO. 38910	DR.# 7	DOCTOR AKELLA MD	LOCATION BRADENTON HEART CENT	D.O.B. [REDACTED]	TODAY'S CH [REDACTED]
T NO. 636	RESPONSIBLE PARTY [REDACTED]		PH. [REDACTED]	REFERRING DR. BHAMBER	ADJUSTMENT [REDACTED]

F		ADDRESS		CITY/STATE		ZIP CODE						TODAY'S PAY	
OVER 90	OVER 60	OVER 30	CURRENT	TOTAL DUE	PT	BC	CS	PAY CHOICE					
0.00	0.00	0.00	2976.00	2976.00	8	4	0						

ANCE COMPANY ICAID CONSULTEC	BA	SCT	POLICY I.D.	RELATIONSHIP TO INSURED				BALANCE DUE
	1			S E L	S P O S E	C H I L D	O T H E R	
4 #			428.8	CONGESTIVE HEART FAILURE				

Medications	Date	Size	Frequen	Count

CHARGE	
DEBITS	
CREDIT	
PAYMENT	

I hereby authorize my insurance benefits to be paid directly to the above signed physician, realizing I am responsible to pay non-covered services and hereby authorize the release of pertinent medical information to insurance carriers.

Patient Signature

DIAGNOSIS		CODE	DIAGNOSIS	CODE	DIAGNOSIS	CODE	DIAGNOSIS	NEXT APPT. WHEN			
13 2° AV BLK I		785.9	Carotid Bruit	272.0	Hypercholesterolemia	445.02	S/P ICD	OV			
12 2° AV BLK II		433.10	Carotid Occlusion	272.4	Hyperlipidemia	445.01	S/P Pacemaker	Test Results			
4 Abdom Aortic Aneurysm		433.11	Cerebrovascular Disease	401.9	Hypertension	445.82	S/P Stent	Spect Myoview			
31 Abnormal EKG		786.50	Chest Pain	458.9	Hypotension	451.0	Superficial Veins	Persantine Myoview			
30 Abnormal Function Study		428.32	Chronic Diastolic Heart Failure	396.9	Mitral/Aortic Valve Dis.		Thrombophlebitis	Rest/Stress RNA			
31 Acute Diastolic Heart Failure		418.9	Chronic Pulmonary Heart Dis.	394.0	Mitral Stenosis	780.2	Syncope	Adenosine Myoview			
33 Acute on Chronic Diastolic Heart Failure		428.22	Chronic Systolic Heart Failure	424.0	Mitral Valve Disorder	427.0	Tachycardia, Paroxysmal	Dobutamine Stress			
23 Acute on Chronic Systolic Heart Failure		428.0	Congestive Heart Failure	412	Old MI		Supra Vent.	Muga Scan			
121 Acute Systolic Heart Failure		496	COPD	780.79	Other Malaise + Fatigue	427.1	Tachycardia, Ventricular,	Regular Stress			
19 Angina Pectoris		414.06	Coronary Atherosclerosis of	785.1	Palpitations		Paroxysmal	Echo w/Color/Doppler			
10 Aortic Stenosis Rheumatic			Coronary Artery of Transp. Heart	423.9	Pericardial Effusion	427.41	Tachycardia, Vent. FIB	Echo Limited			
1 Aortic Valve Disorder		790.92	Coumadin Therapy	420.90	Pericarditis	427.42	Tachycardia, Vent. Flutter	T-wave			
9 Arrhythmia/Cardiac Dysrhythmia		395.9	Diseases of Aortic Valve	443.9	Peripheral Vascular Disease	414.9	Transient Cardiac Ischemia	Stress Echo			
18 Atheroscl. Lwr Ext Art		394.9	Diseases of Mitral Valve	425.4	Pre Op Cardiovascular	435.9	Transient Cerebral Ischemia	Carotid Duplex			
31 Atrial Fibrillation		414.12	Dissection of Coronary Artery	425.4	Primary Cardiomyopathy	397.0	Tric. Insuf. Rheumatic	Lower Arterial w/PVR			
32 Atrial Flutter		780.4	Dizziness	415.19	Pulmonary Embolism	424.2	Tricuspid Insuf.	Lower Arterial Duplex			
15 Atrial Septal Defect		250.00	DM-Adult Onset	416.0	Pulmonary HTN-Primary	428.20	Unsp. Systolic Heart Failure	Lower Venous			
10 Atrioventricular Block-Complete		250.01	DM-Insulin Dependent	416.8	Pulmonary HTN-Secondary	411.1	Unstable Angina	Renal Duplex			
11 Benign HYP HRT		451.11	DVT Femoral Vein	442.3	Pseudoaneurysm	444.21	Upper Extremity Occlusion	Aorta			
89 Bradycardia		451.19	DVT Pop. Tibial	398.90	Rheumatic Heart Disease	443.3	Valve Replacement	Holter			
102 CAD, Auto Bypass		782.3	Edema	786.05	Shortness of Breath	454	Varicose Veins Lwr Ext	Pacer Check			
101 CAD, Native		276.6	Fluid Retention	427.81	Sinoatrial Node Dysfunction SSS		Specify	ICD Check			
100 CAD, unsp.		785.2	Heart Murmur	445.81	S/P CABG/Bypass	593.81	Vascular Disorder of Kidney,	EKG			
								Renal Artery Thrombosis	Blood Pressure Check		
								459.81	Venous Insuff.	ICG	
								453.8	Venous Thrombosis Upper Ext	Lipid Clinic	
								795.2	White Coat Hypertension	Cardiac Rehab	
								426.7	Wolff-Parkinson-White Disease	Coumadin Clinic	
									ECP		

OFFICE VISITS		FEE	✓	CODE	NONINVASIVE PROCEDURES	FEE
201	Level I	99211	Level I	90782	Therapeutic Injection	
202	Level II	99212	Level II	78481	Rest RNA/First Pass	
203	Level III	99213	Level III	93015	Exercise Stress Test	
204	Level IV	99214	Level IV	78478	Myocardial Perfusion	
205	Level V	99215	Level V	78465	Tomographic Spect Multiple	
204	Post Op Visit			78480	Perfusion Study w/Elec Fac	
CONSULTATIONS				A9500	Cardiolite	
241	Level I			A9502	Myoview per dose	
242	Level II			J1245	Persantine	
243	Level III			J1250x1	Dobutamine	
244	Level IV			J0151	Adenosine	
245	Level V			J0280	Aminophylline	
DESCRIPTION				W4132x1	MUGA	
2061	Lipid Panel			78472	MUGA	
1450	AST-SGOT			93025	Micro-volt T-wave Alternans	
1460	ALT-SGPT			93306	Echocardiogram-Complete	
1000	EKG with Report			93320	Cardiac Doppler	
1278	Signal Avg. EKG			93325	Cardiac Doppler Color Flow	
1040	Rhythm Strip			93321	Cardiac Doppler Limited	
1288	Pacer Evaluation-Single/Dual			93350	Echo w/Exercise (93015)	
1280	Pacer Reprogram-Dual			93308	Echo Limited	
1279	Pacer Reprogram-Single			93701	Bio-Z 1 or 2	
1289	ICD Eval & Report-Single/Dual			93880	Carotid Imaging, Real Time	
1282	ICD Single Reprogram			93922	Lwr Art BP-ABI	
1283	ICD Dual Reprogram			93923	Up/Lwr Art BP PVR/Rest	
1277	Elec. Analysis Implantable Loop Records			93924	Up/Lwr Art BP PVR/Exercise	
1270	Hook up Loop Monitor			93925	Lower Arterial Imaging	
1272	Interp Loop Monitor			93926	Limited Arterial Imaging	
1014	Interp Non Loop Monitor			93930	Upper Arterial Imaging	
1230	Holter Monitor Global			93965	Lower Ext Venous CW, PPG	
1001	Venipuncture			93970	Lower Venous Imaging	
1610	Protime			93971	Upper Venous Imaging	
1940	IV Lasix 20mg			93975	Renal Duplex	
1160	IV Digoxin			93978	Aorta-Iliac Ultrasound	
1460	Atropine			93784	24° BP Monitor	
				J7051	Saline 5cc	
				160166	ECP	
				93979	CELIAC Ultrasound	

TIME	PATIENT	REASON	PRIOR BALANCE
1/12/17 3:30	S.S.	PACER CHECK	1712.00
			INS 0.00

ET NO.	DR. #	DOCTOR	LOCATION	D.O.B.	TODAY'S CHARGE
111234	12	PACER	BRADENTON HEART CENT		

ENT NO.	RESPONSIBLE PARTY	PH#	REFERRING DR.	ADJUSTMENTS

M	F	ADDRESS	CITY/STATE	ZIP CODE
	X			

OVER 90	OVER 60	OVER 30	CURRENT	TOTAL DUE	PT	BC	CS	PAY CHOICE	TODAY'S PAYMENT
712.00	0.00	0.00	0.00	1712.00	15	4	2		

INSURANCE COMPANY	BA	SC	POLICY I.D.	RELATIONSHIP TO INSURED	BALANCE DUE
CBS FLORIDA	Y	I		S E L F	
450.00 OV COPAY		I		S P O U S E	
ISN #			427.89 BRADYCARDIA	C H I L D	
				O T H E R	

I hereby authorize my insurance benefits to be paid directly to the above signed physician, realizing I am responsible to pay non-covered services and hereby authorize the release of pertinent medical information to insurance carriers.

Patient Signature

L.H.

CPT	OFFICE SERVICES	FEE	CPT	OFFICE SERVICES	FEE	CPT	MISCELLANEOUS	FEE
ESTABLISHED PATIENTS			COUMADIN CLINIC			J0280	Aminophylline _____ MG	
99211	Level 1, Minimal		99211	Level 1 Visit BP Check		J0460	Atropine _____ MG	
99212	Level 2, Minor		85610	Protime / INR		J3490	Lopressor _____ MG	
99213	Level 3, Expanded Moderate					J1940	Furosemide Inj Per 20 mg	
99214	Level 4, Detailed Moderate		ECHO/VASCULAR ULTRASOUND			J0152	Adenosine _____ MG = _____ Units	
99215	Level 5, Comprehensive High		93308	Echo Limited & Follow Up		J1245	Persantine _____ MG	
NEW PATIENTS			93880	Carotid Duplex Scan		A9500	Cardiolite x 2 Units	
99201	Level 1, Minor		93926	Duplex Scan Limited/Unilat		J1250	Dobutamine _____ MG	
99202	Level 2, Expanded Moderate		93978	Ultrasound of Abdomen				
99203	Level 3, Detailed Moderate		93306	Echo/Doppler/Color Flow				
99204	Level 4, Comprehensive High							
99205	Level 5, High Complexity							
CONSULTS			NUCLEAR			SCHEDULE FOR		
99241	Level 1, Minor		93015	Exercise Stress Test		<input type="radio"/> <u>Stress Test</u> _____ Exercise _____ Cardiolite		
99242	Level 2, Expanded Moderate		78465	Spect Camera		<input type="radio"/> Adenosine _____ Persantine _____ Dobutamine		
99243	Level 3, Detailed Moderate		78478	Gated Study		<input type="radio"/> <u>Muga Scan</u>		
99244	Level 4, Comprehensive High		78480	Gated Ejection Fraction		<input type="radio"/> <u>Echocardiogram</u>		
99245	Level 5, High Complexity		78472	Muga Scan		<input type="radio"/> <u>Carotid Ultrasound</u>		
			Q3010	Technetium 99m 25mci		<input type="radio"/> <u>Holter Monitor</u>		
EKG / HOLTER			94761	Pulse Oximetry w/ Exercise		<input type="radio"/> <u>Event Monitor</u>		
93000	EKG w/ Interp					<input type="radio"/> <u>Office Visit</u>		
93224	Holter Monitor		PACEMAKER / ICD			In: _____ <u>Near Future</u> _____ <u>Weeks</u>		
93270	Event Monitor Hookup		93288	Interrogation Pacemaker (Single/Dual/Bi-V)		_____ <u>Months</u> _____ <u>Years</u>		
93272	Event Monitor Interp		93279	Pacemaker Programming (Single)		Refer to: _____		
			93280	Pacemaker Programming (Dual)		_____		
			93281	Pacemaker Programming (Bi-V)		_____		
			93289	Interrogation ICD (Single/Dual/Bi-V)		_____		
			93282	ICD Programming (Single)		<input type="radio"/> <u>Record Request to:</u> _____		
			93283	ICD Programming (Dual)		<input type="radio"/> <u>Cardiac Clearance Letter</u>		
			93284	ICD Programming (Bi-V)				

DATE		TIME		PATIENT	REASON		PRIOR BALANCE	
05/27/09		2:15P		M.M.	OV/EKG/6 MO F/U		.00	
TICKET NO.		DR.#		DOCTOR	LOCATION		D.O.B.	
252		252			252		252	
PATIENT NO.		RESPONSIBLE PARTY		PH#		REFERRING DR.		TODAY'S CHARGE
M		F		ADDRESS		CITY/STATE		ZIP CODE
OVER 90		OVER 60		OVER 30		CURRENT		TOTAL DUE
								.00
PT		BC		CS		PAY CHOICE		TODAY'S PAYMENT
INSURANCE COMPANY		BA		SCT		POLICY I.D.		RELATIONSHIP TO INSURED
								SELF
MEDICARE PART B								SPOUSE
AARP HEALTHCARE OPTIONS								CHILD
EXPECTED COPAY:								OTHER
								BALANCE DUE

[illegible]



John K. Lourie, M.D., FACC
Advanced Cardiology

Procedures

- | | |
|---|---|
| <input type="checkbox"/> 93288 - PM DEVICE EVAL IN PERSON | <input type="checkbox"/> 93289 - ICD DEVICE INTERROGATE |
| <input type="checkbox"/> 93279 - PM DEVICE PROGR EVAL, SNGL | <input type="checkbox"/> 93282 - ICD DEVICE PROG EVAL, 1 SNGL |
| <input type="checkbox"/> 93280 - PM DEVICE PROGR EVAL, DUAL | <input type="checkbox"/> 93283 - ICD DEVICE PROGR EVAL, DUAL |
| <input type="checkbox"/> 93281 - PM DEVICE PROGR EVAL, MULTI | <input type="checkbox"/> 93284 - ICD DEVICE PROGR EVAL, MULT |
| <input type="checkbox"/> 93294 - PM DEVICE INTERROGATE REMOTE | <input type="checkbox"/> 93295 - ICD DEVICE INTERROGAT REMOTE |
| <input type="checkbox"/> 93296 - PM/ICD REMOTE TECH SERV | |

Diagnoses

- | | |
|---|---|
| <input type="checkbox"/> V45.01 - CARDIAC PACEMAKER IN SITU | <input type="checkbox"/> V45.02 - AICD IN SITU |
| <input type="checkbox"/> 427.31 - ATRIAL FIBRILLATION | <input type="checkbox"/> 427.32 - ATRIAL FLUTTER |
| <input type="checkbox"/> 427.89 - CARDIAC DYSRHYTHMIAS OT | <input type="checkbox"/> 427.69 - PREMATURE BEATS OT |
| <input type="checkbox"/> 427.41 - VENTRICULAR FIBRILLATION | <input type="checkbox"/> 427.42 - VENTRICULAR FLUTTER |
| <input type="checkbox"/> 427.1 - PAROX VENTRICULR TACHYCARDIA | |

Patient Demographics

First Name:	[REDACTED] M.	Last Name:	[REDACTED] C.
Patient #:	5823	Medical Record #:	4872
DOB:	[REDACTED]	Home Phone:	[REDACTED]
Home Address 1:	[REDACTED]	Home City:	[REDACTED]
Home State:	Florida	Home Postal Code:	[REDACTED]
Referring Physician:		Appt. Date/Time:	11/04/2009 09:45
Appt. Reason:	MEDTRONIC PACEMAKER CHECK	Primary Insurance:	MEDICARE -> MEDICARE PART B
Secondary Insurance:		Copay Due:	
Patient Balance:	\$0.00		

Additional Information

next check:

☐ 1 month

☐ 2 months

☐ 3 months

EXHIBIT 8

Advanced Cardiology
PACEMAKER/ICD TESTING

Procedures

- | | |
|--|---|
| <input type="checkbox"/> 93288 - PM DEVICE EVAL IN PERSON | <input type="checkbox"/> 93289 - ICD DEVICE INTERROGATE |
| <input type="checkbox"/> 93279 - PM DEVICE PROGR EVAL, SNGL | <input type="checkbox"/> 93282 - ICD DEVICE PROG EVAL, 1 SNGL |
| <input checked="" type="checkbox"/> 93280 - PM DEVICE PROGR EVAL, DUAL | <input type="checkbox"/> 93283 - ICD DEVICE PROGR EVAL, DUAL |
| <input type="checkbox"/> 93281 - PM DEVICE PROGR EVAL, MULTI | <input type="checkbox"/> 93284 - ICD DEVICE PROGR EVAL, MULT |
| <input type="checkbox"/> 93294 - PM DEVICE INTERROGATE REMOTE | <input type="checkbox"/> 93295 - ICD DEVICE INTERROGAT REMOTE |

Diagnoses

- | | |
|---|---|
| <input type="checkbox"/> V45.01 - CARDIAC PACEMAKER IN SITU | <input type="checkbox"/> V45.02 - AICD IN SITU |
| <input type="checkbox"/> 427.31 - ATRIAL FIBRILLATION | <input type="checkbox"/> 427.32 - ATRIAL FLUTTER |
| <input type="checkbox"/> 427.89 - CARDIAC DYSRHYTHMIAS OT | <input type="checkbox"/> 427.69 - PREMATURE BEATS OT |
| <input type="checkbox"/> 427.41 - VENTRICULAR FIBRILLATION | <input type="checkbox"/> 427.42 - VENTRICULAR FLUTTER |
| <input type="checkbox"/> 427.1 - PAROX VENTRICULR TACHYCARDIA | |

Patient Demographics

Appt. Date/Time:	07/28/2010 09:30	Appt. Reason:	MEDTRONIC PACEMAKER CHECK
First Name:	[REDACTED] V.	Last Name:	[REDACTED] C.
Patient #:	611	DOB:	[REDACTED]
Home Address 1:	[REDACTED]	Home City:	[REDACTED]
Home State:	Florida	Home Postal Code:	[REDACTED]
Home Phone:	[REDACTED]	Primary Insurance:	MEDICARE -> MEDICARE PART B
Secondary Insurance:	BCBS -> BCBS FL BLUE OPTIONS	Referring Physician:	
Copay Due:		Patient Balance:	-\$17.42

Additional Information

next check:

- ☐ 1 month
☐ 2 months
☐ 3 months

Advanced Cardiology PACEMAKER/ICD TESTING

Procedures

- | | |
|---|---|
| <input type="checkbox"/> 93288 - PM DEVICE EVAL IN PERSON | <input type="checkbox"/> 93289 - ICD DEVICE INTERROGATE |
| <input type="checkbox"/> 93279 - PM DEVICE PROGR EVAL, SNGL | <input type="checkbox"/> 93282 - ICD DEVICE PROG EVAL, 1 SNGL |
| <input type="checkbox"/> 93280 - PM DEVICE PROGR EVAL, DUAL | <input type="checkbox"/> 93283 - ICD DEVICE PROGR EVAL, DUAL |
| <input type="checkbox"/> 93281 - PM DEVICE PROGR EVAL, MULTI | <input type="checkbox"/> 93284 - ICD DEVICE PROGR EVAL, MULT |
| <input type="checkbox"/> 93294 - PM DEVICE INTERROGATE REMOTE | <input type="checkbox"/> 93295 - ICD DEVICE INTERROGAT REMOTE |
| <input type="checkbox"/> 93296 - PM/ICD REMOTE TECH SERV | |

Diagnoses

- | | |
|---|---|
| <input type="checkbox"/> V45.01 - CARDIAC PACEMAKER IN SITU | <input type="checkbox"/> V45.02 - AICD IN SITU |
| <input type="checkbox"/> 427.31 - ATRIAL FIBRILLATION | <input type="checkbox"/> 427.32 - ATRIAL FLUTTER |
| <input type="checkbox"/> 427.89 - CARDIAC DYSRHYTHMIAS OT | <input type="checkbox"/> 427.69 - PREMATURE BEATS OT |
| <input type="checkbox"/> 427.41 - VENTRICULAR FIBRILLATION | <input type="checkbox"/> 427.42 - VENTRICULAR FLUTTER |
| <input type="checkbox"/> 427.1 - PAROX VENTRICULR TACHYCARDIA | |

Patient Demographics

Appt. Date/Time:	06/16/2010 09:45	Appt. Reason:	MEDTRONIC ICD REPROGRAMMING
First Name:	[REDACTED] C.	Last Name:	[REDACTED] C.
Patient #:	537	DOB:	[REDACTED]
Home Address 1:	[REDACTED]	Home City:	[REDACTED]
Home State:	Florida	Home Postal Code:	[REDACTED]
Home Phone:	[REDACTED]	Primary Insurance:	MEDICARE -> MEDICARE PART B
Secondary Insurance:	BCBS -> BCBS FL BLUE OPTIONS	Referring Physician:	
Copay Due:		Patient Balance:	-\$28.36

Additional Information

next check:

☐ 1 month

☐ 2 months

☐ 3 months

Abnormal (ECG)(EKG)	794.31	<input type="checkbox"/> Carotid Bruit	785.9	<input type="checkbox"/> Heart Murmur	785.2	<input type="checkbox"/> Pulmonary Hypertension	416.8
Abnormal Func Std, unspec	794.30	<input type="checkbox"/> Carotid Stenosis	433.10	<input type="checkbox"/> Hematoma, Common Femoral	904.0	<input type="checkbox"/> Renal Artery Stenosis	440.1
Amaurosis Fugax	362.34	<input type="checkbox"/> Chest Pain	786.50	<input type="checkbox"/> Hyperlipidemia	272.4	<input type="checkbox"/> Renovascular Hypertension	403.90
Anemia	285.9	<input type="checkbox"/> Chest Pain, precordial	786.51	<input type="checkbox"/> Hypertension, benign	401.1	<input type="checkbox"/> Shortness of Breath/Dyspnea	786.05
Aneurysm, Abdominal Aortic	441.4	<input type="checkbox"/> Chest Tightness/Pressure	786.59	<input type="checkbox"/> Hypertension, malignant	401.0	<input type="checkbox"/> Sick Sinus Syndrome	427.81
Aneurysm, Thoracic	441.2	<input type="checkbox"/> Congestive Heart Failure	428.0	<input type="checkbox"/> Hypotension, Chronic	458.1	<input type="checkbox"/> Subclavian Steal	435.2
Angina, NOS	413.9	<input type="checkbox"/> CHF w/ Pulmonary Edema	428.1	<input type="checkbox"/> Hypotension, Orthostatic	458.0	<input type="checkbox"/> Syncope	780.2
Angina, Unstable	411.1	<input type="checkbox"/> COPD	496	<input type="checkbox"/> Hypothyroidism	244.9	<input type="checkbox"/> Tachycardia, Unspec.	785.0
Aortic Insufficiency	424.1	<input type="checkbox"/> Coumadin Therapy	790.92	<input type="checkbox"/> ICD	V45.02	<input type="checkbox"/> Tachycardia, SVT	427.0
Aortic Stenosis	424.1	<input type="checkbox"/> Diabetes-NIDDM, unspec	250.00	<input type="checkbox"/> LVH-Left Ventricular Hypertrophy	402.90	<input type="checkbox"/> Tachycardia, Ventricular	427.1
Aortic Valve Disorder	424.1	<input type="checkbox"/> Diabetes-IDDM, unspec	250.01	<input type="checkbox"/> Mass, Lump in Chest	786.6	<input type="checkbox"/> Transient Ischemic Attack	435.9
Atherosclerosis of Aorta	440.0	<input type="checkbox"/> Diaphoresis	780.8	<input type="checkbox"/> Mitral Regurgitation	424.0	<input type="checkbox"/> Tricus Valve Disorder, Non Rheum.	424.2
Atherosclerosis Extremity w/ claud	440.21	<input type="checkbox"/> Dizziness/Vertigo	780.4	<input type="checkbox"/> Mitral Valve Disorder	424.0	<input type="checkbox"/> Venous Insufficiency, unspec	459.81
Atherosclerosis of Renal	440.1	<input type="checkbox"/> Edema	782.3	<input type="checkbox"/> Myocardial Infarction-Old	412	<input type="checkbox"/> Ventricular Fibrillation	427.41
Atrial Fibrillation	427.31	<input type="checkbox"/> Embolism - Arterial	444.9	<input type="checkbox"/> Myocardial Infarction-Recent	410.90	<input type="checkbox"/> Ventricular Flutter	427.42
Atrial Flutter	427.32	<input type="checkbox"/> Extremity Pain	729.5	<input type="checkbox"/> Numbness	782.0	<input type="checkbox"/> Ventricular Premature Contractions	427.69
Atrial Premature Contractions	427.61	<input type="checkbox"/> Extremity Swelling	729.81	<input type="checkbox"/> Pacemaker	V45.01	<input type="checkbox"/> Ventricular Tachycardia	427.1
Basilar Syndrome	435.0	<input type="checkbox"/> Fatigue/Chronic Syndrome	780.71	<input type="checkbox"/> Palpitations	785.1	<input type="checkbox"/> Vertebral Syndrome	435.1
Bradycardia	427.89	<input type="checkbox"/> Fatigue/Malaise	780.79	<input type="checkbox"/> Peripheral Vascular Disease	443.9	<input type="checkbox"/> Wolf Parkinson White Disease	426.7
CAD-Native Vessel	414.01	<input type="checkbox"/> GERD	530.11	<input type="checkbox"/> Phlebitis, Femoral	451.11	<input type="checkbox"/> Other Diagnosis: _____	
CAD-Autologous BPG	414.02	<input type="checkbox"/> Heart Block, 1st Degree	426.11	<input type="checkbox"/> Phlebitis, Iliac	451.81		
Cardiac Rhythm Regulators	E942.0	<input type="checkbox"/> Heart Block, Complete	426.0	<input type="checkbox"/> Phlebitis, Popliteal	451.19		
Cardiomegaly	429.3	<input type="checkbox"/> Heart Block, LBBB Hemiblock	426.2	<input type="checkbox"/> Phlebitis, Superficial	451.0		
Cardiomyopathy	425.4	<input type="checkbox"/> Heart Block, LBBB	426.3	<input type="checkbox"/> Pleural Effusion	511.9		
Cardiomyopathy, Ischemic	414.8	<input type="checkbox"/> Heart Block, RBBB	426.4	<input type="checkbox"/> Pseudaneurysm	442.2		

MISYS HEALTHCARE SYSTEMS (888) 633-3676

 PO# 779294
 JOB# 64522

Telephone: [REDACTED]

OFFICE VISITS				FEE	CPT	✓	PACEMAKER / AICD	FEE	CPT	✓	NUCLEAR	FEE
9201	99211	99241	Level 1		93288		Pacemaker Eval & Report		93015		Exercise Treadmill	
9202	99212	99242	Level 2		93279		Pacemaker Reprog - Single		78465		Spect Camera	
9203	99213	99243	Level 3		93280		Pacemaker Reprog - Double		78478		Gated Study	
9204	99214	99244	Level 4		93289		ICD Eval & Report		78480		Gated Ejection Fraction	
9205	99215	99245	Level 5		93282		ICD Single Reprogramming		78472		Cardiac Blood Pool Rest	
	99024		Post Op Visit		93283		ICD Dual Reprogramming		78496		Cardiac Blood Pool Single	
	99354		Prolonged OV		93293		TIM Check		A9500		Cardiolite	
8446			E-RX attempt-Unable		93281		Initial PR Pacer		A9502		Myoview	
8443			E-RX's done		93284		Initial PR ICD		A9595		Thallium	
8445			No RX's needed						J1250		Dobutamine	
DIAGNOSTIC									J0152		Adenosine	
ECHO / TEE					93880		Carotid Duplex		A9580		Tech RBC's-Muga	
06			Echo		93882		Carotid limited/unilat		J0460		Atropine	
20			Cardiac Doppler		93922		UEA/LEA single level		J3490L		Lopressor	
25			Doppler Color Flow		93923		UEA/LEA multiple level		93784		24 Hr Blood Pressure	
EKG					93924		UEA/LEA w/ exercise		94760		Pulse Ox	
00			EKG w/report		93925		Duplex Arterial lower					
78			Signal Avg EKG		93926		Duplex limited/unilat					
40			Rhythm Strip		93978		Duplex Aorta iliac		85610		Protine	
HOLTER / EVENT MONITOR					93979		Duplex Aorta limited/unilat		83721		Direct LDL	
24			Holter Monitor		93970		Duplex Venous		80061		Lipid Profile	
70			Hook up Loop Monitor		93971		Duplex Venous limited/unilat		84460		AST/ALT	
72			Interp Loop Monitor		93978		Duplex Venacava iliac		36415		Fingerstick	
14			Interp Non Loop Monitor		93965		Quant Venous Flow Studies		83880		BNP	
					93930		Duplex Arterial Upper					
					93975		Duplex Renal					
					93976		Renal Ultrasound (No Duplex)					
					76705		Limited Abdominal Ultrasound					

DIAGNOSIS			
Abnormal (ECG)(EKG)	794.31	<input type="checkbox"/> Carotid Bruit	785.9
Abnormal Func Std, unspc	794.30	<input type="checkbox"/> Carotid Stenosis	433.10
Amaurosis Fugax	362.34	<input type="checkbox"/> Chest Pain	786.50
Anemia	285.9	<input type="checkbox"/> Chest Pain precordial	786.51
Aneurysm, Abdominal Aortic	441.4	<input type="checkbox"/> Chest Tightness/Pressure	786.59
Aneurysm, Thoracic	441.2	<input type="checkbox"/> Congestive Heart Failure	428.0
Angina, NOS	413.9	<input type="checkbox"/> CHF w/ Pulmonary Edema	428.1
Angina, Unstable	411.1	<input type="checkbox"/> COPD	496
Aortic Insufficiency	424.1	<input type="checkbox"/> Coumadin Therapy	790.92
Aortic Stenosis	424.1	<input type="checkbox"/> Diabetes-NIDDM, unspc	250.00
Aortic Valve Disorder	424.1	<input type="checkbox"/> Diabetes-IDDM, unspc	250.01
Atherosclerosis of Aorta	440.0	<input type="checkbox"/> Diaphoresis	780.8
Atherosclerosis Extremity w/ claud	440.21	<input type="checkbox"/> Dizziness/Vertigo	780.4
Atherosclerosis of Renal	440.1	<input type="checkbox"/> Edema	782.3
Atrial Fibrillation	427.31	<input type="checkbox"/> Embolism - Arterial	444.9
Atrial Flutter	427.32	<input type="checkbox"/> Extremity Pain	729.5
Atrial Premature Contractions	427.61	<input type="checkbox"/> Extremity Swelling	729.81
Basilar Syndrome	435.0	<input type="checkbox"/> Fatigue/Chronic Syndrome	780.71
Bradycardia	427.89	<input type="checkbox"/> Fatigue/Malaise	780.79
CAD-Native Vessel	414.01	<input type="checkbox"/> GERD	530.11
CAD-Autologous BPG	414.02	<input type="checkbox"/> Heart Block, 1st Degree	426.11
Cardiac Rhythm Regulators	E942.0	<input type="checkbox"/> Heart Block, Complete	426.0
Cardiomegaly	429.3	<input type="checkbox"/> Heart Block, LBBB Hemiblock	426.2
Cardiomyopathy	425.4	<input type="checkbox"/> Heart Block, LBBB	426.3
Cardiomyopathy, Ischemic	414.8	<input type="checkbox"/> Heart Block, RBBB	426.4
		<input type="checkbox"/> Heart Murmur	785.2
		<input type="checkbox"/> Hematoma, Common Femoral	904.0
		<input type="checkbox"/> Hyperlipidemia	272.4
		<input type="checkbox"/> Hypertension, benign	401.1
		<input type="checkbox"/> Hypertension, malignant	401.0
		<input type="checkbox"/> Hypotension, Chronic	458.1
		<input type="checkbox"/> Hypotension, Orthostatic	458.0
		<input type="checkbox"/> Hypothyroidism	244.9
		<input type="checkbox"/> ICD	V45.02
		<input type="checkbox"/> LVH-Left Ventricular Hypertrophy	402.90
		<input type="checkbox"/> Mass, Lump in Chest	786.8
		<input type="checkbox"/> Mitral Regurgitation	424.0
		<input type="checkbox"/> Mitral Valve Disorder	424.0
		<input type="checkbox"/> Myocardial Infarction-Old	412
		<input type="checkbox"/> Myocardial Infarction-Recent	410.90
		<input type="checkbox"/> Numbness	782.0
		<input type="checkbox"/> Pacemaker	V45.01
		<input type="checkbox"/> Palpitations	785.1
		<input type="checkbox"/> Peripheral Vascular Disease	443.9
		<input type="checkbox"/> Phlebitis, Femoral	451.11
		<input type="checkbox"/> Phlebitis, Iliac	451.81
		<input type="checkbox"/> Phlebitis, Popliteal	451.19
		<input type="checkbox"/> Phlebitis, Superficial	451.0
		<input type="checkbox"/> Pleural Effusion	511.9
		<input type="checkbox"/> Pseudotumorism	442.2
		<input type="checkbox"/> Pulmonary Hypertension	416.8
		<input type="checkbox"/> Renal Artery Stenosis	440.1
		<input type="checkbox"/> Renovascular Hypertension	403.90
		<input type="checkbox"/> Shortness of Breath/Dyspnea	786.05
		<input type="checkbox"/> Sick Sinus Syndrome	427.81
		<input type="checkbox"/> Subclavian Steal	435.2
		<input type="checkbox"/> Syncope	780.2
		<input type="checkbox"/> Tachycardia, Unspec.	785.0
		<input type="checkbox"/> Tachycardia, SVT	427.0
		<input type="checkbox"/> Tachycardia, Ventricular	427.1
		<input type="checkbox"/> Transient Ischemic Attack	435.9
		<input type="checkbox"/> Tricus Valve Disorder, Non Rheum.	424.2
		<input type="checkbox"/> Venous Insufficiency, unspc	459.81
		<input type="checkbox"/> Ventricular Fibrillation	427.41
		<input type="checkbox"/> Ventricular Flutter	427.42
		<input type="checkbox"/> Ventricular Premature Contractions	427.69
		<input type="checkbox"/> Ventricular Tachycardia	427.1
		<input type="checkbox"/> Vertebral Syndrome	435.1
		<input type="checkbox"/> Wolf Parkinson White Disease	426.7
		<input type="checkbox"/> Other Diagnosis:	

TIME PATIENT 01/28/09 9:00A		REASON J.L. 1 YEAR RETURN		PRIOR BALANCE .00	
SET NO. DR.# DOCTOR		LOCATION		D.O.B.	
PATIENT NO. RESPONSIBLE PARTY		PH#		REFERRING DR.	
M	F	ADDRESS		CITY/STATE	ZIP CODE
OVER 90		OVER 60		OVER 30	CURRENT
TOTAL DUE		PT		BC	CS
PAY CHOICE		TODAY'S CHARGE		ADJUSTMENTS	
TODAY'S PAYMENTS		BALANCE DUE		NEXT APPOINTMENT:	
Days		Weeks		Months	

154A PONS 1519 (UL)

117. Denton, FL 34209

761-4448 Fax (941) 761-0235

Billings Inquiries (941) 379-7872

11) #65-1094378

Robert J. Subbionda, MD, FACC

Joseph N. Pace MD FACC

Joseph M. Demaree: MD, FACC

Laura Webb PAs

Wirtschaftsrecht

SECRET

Case 8:13-cv-01851-SLD-EJS Document 164-6 Filed 08/18/17 Page 58 of 57

[illegible]

3101 61st Street West
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FD #65-1094378

Robert J. Subbiondo, MD, FACC
Joseph N. Pace, MD, FACC
Joseph M. Branconi, MD, FACC
Laura Webb, PA-C
Kimberly French, ARNP
Carol (Kelly) Harrington, ARNP

CODE	DIAGNOSIS	CODE	DIAGNOSIS	CODE	DIAGNOSIS	CODE	DIAGNOSIS	NEXT APPT.	WHEN
441.2	Thoracic Aneurysm w/o Rupture	433.10	Carotid Occlusion	424.0	Mitral Valve Disorder	440.22	Atherosclerosis w/Rest Pain		
441.4	Abdom Aortic Aneurysm	433.11	Cerebrovascular Disease	412	Old MI	593.81	Renal Artery Stenosis		
794.31	Abnormal EKG	786.50	Chest Pain	780.79	Other Malaise + Fatigue	729.81	Edema-Lower Extremity		
794.30	Abnormal Function Study	428.0	Congestive Heart Failure	765.1	Palpitations	729.5	Pain-Lower Extremity		
410	Acute Myocardial Inf Wall	456	COPD	443.9	Peripheral Vascular Disease	745.5	Atrial Septal Defect		
413.9	Angina Pectoris	414.00	CAD, unsp.	281.0	Perilicious Anemia	746.4	Bicuspid Aortic Valve		
356.0	Aortic Stenosis Rheumatic	414.01	CAD, Native	442.3	Pseudoaneurysm - LE	747.0	Patent Ductus Arteriosus		
356.1	Aortic Valve Insufficiency	414.02	CAD, Auto Bypass	414.06	Coronary Atherosclerosis of Coronary Artery of Transp. Heart	416.9	Chronic Pulmonary Heart Dis.		
395.9	Aortic Valve Disorder (Non-Rheumatic)	790.92	Coumadin Therapy	428.0	Congestive Heart Failure Unspecified	786.05	Shortness of Breath		
424.1	Aortic Valve Disorder	760.4	Dizziness	414.12	Dissection of Coronary Artery	427.81	Sinoatrial Node Dysfunction SSS		
427.9	Arrhythmia/Cardiac Dysrhythmia	250.00	DM-Adult Onset	428.20	Unspecified Systolic Heart Failure	445.81	S/P CABG/Bypass		
440.8	Atheroscl. Lwr Ext Art	250.01	DM-Insulin Dependent	428.21	Acute Systolic Heart Failure	451.0	Superficial Veins Thrombophlebitis		
427.31	Atrial Fibrillation	451.11	DVT Femoral Vein	428.22	Chronic Systolic Heart Failure	780.2	Syncope		
427.32	Atrial Flutter	451.19	DVT Pop. Tibial	428.31	Acute Diastolic Heart Failure	427.0	Tachycardia, Paroxysmal Supra Vent.		
426.0	Arrhythmia/Block-Complete	765.2	Heart Murmur	428.32	Chronic Diastolic Heart Failure	427.1	Tachycardia, Ventricular, Paroxysmal		
427.89	Bradycardia	401.9	Hypertension	428.40	Unspec. Comb. Systolic & Diastolic Heart Failure	427.41	Tachycardia, Vent. FIB		
426.13 2° AV BLK I		458.9	Hypotension	415.19	Pulmonary Embolism	427.42	Tachycardia, Vent. Flutter		
426.12 2° AV BLK II		272.0	Hypercholesterolemia	398.90	Rheumatic Heart Disease	435.9	Transient Cerebral Ischemia		
442.0	Cardiac Rhythm Regulators	272.4	Hypertension	402.10	Hypertensive Heart	397.0	Tricuspid Valve Disease		
442.1	Cardioactive Glycosides & Drugs	396.9	Mitral/Aortic Valve Dis.	414.8	Ischemic Heart Disease	424.2	Tricuspid Insuf.		
765.9	Carotid Bruit	394.0	Mitral Stenosis	425.4	Cardiomyopathy	411.1	Unstable AP		
		394.1	Mitral Valve Insufficiency	440.21	Atherosclerosis w/Claudication	444.21	Upper Extremity Occlusion		

OFFICE VISITS		FEE		NONINVASIVE PROCEDURES		FEE
NEW	ESTABLISHED					
99201 Level I	99211 Level I			90782	Therapeutic Injection	
99202 Level II	99212 Level II			78481	Rest RNA/First Pass	
99203 Level III	99213 Level III			93015	Exercise Stress Test	
99204 Level IV	99214 Level IV			78478	Myocardial Perfusion	
99205 Level V	99215 Level V			78465	Tomographic Spect Multiple	
99024 Post Op Visit				78480	Perfusion Study w/Ejec Frac	
CONSULTATIONS				A9500x2	Cardiolite per dose	
99241 Level I				J1245	Persantine	
99242 Level II				J1250x1	Dobutamine	
99243 Level III				J0151	Adenosine	
99244 Level IV				W4132x1	MUGA	
99245 Level V				78472	MUGA	
DESCRIPTION				93307	Echocardiogram 2D & M Mode	
93224 Holter Monitor				93320	Cardiac Doppler	
93000 EKG with Report				93233	Holter Physician Review & Int	
93278 Signal Avg. EKG				93321	Cardiac Doppler Limited	
93040 Rhythm Strip				93325	Cardiac Doppler Color Flow	
93734 Pacemaker Evaluation & Report-Sin				93350	Echo w/Exercise (93015)	
93731 Pacemaker Evaluation & Report-Dou				93308	Echo Limited	
93735 Pacemaker Reprogram-Single				93701	Bio-Z 1 or 2	
93732 Pacemaker Reprogram-Double				93880	Carotid Imaging, Real Time	
93741 ICD Single Eval & Report				93922	Lwr Art BP-ABI	
93742 ICD Single Reprogram				93923	Up/Lwr Art BP PVR/Rest	
93743 ICD Dual Eval & Report				93924	Up/Lwr Art BP PVR/Exercise	
93744 ICD Dual Reprogram				93925	Lower Arterial Imaging	
93727 Elec. Analysis Implantable Loop Records				93926	Limited Arterial Imaging	
0280 Aminophylline				93930	Upper Arterial Imaging	
90659 Flu Shot				93965	Lower Ext Venous CW, PPG	
00008 Administration Influenza				93970	Lower Venous Imaging	
93270 Hook up Loop Monitor				93971	Upper Venous Imaging	
93272 Interp Loop Monitor				93975	Renal Duplex	
93014 Interp Non Loop Monitor				93978	Aorta-iliac Ultrasound	
00001 Venipuncture				93784	24" BP Monitor	
25610 Protine				J7051	Saline Scc	
11940 IV Lasix 20mg				36415	Fingersick/Venipuncture	
13420 B-12 Injection				84460	Lipid Profile	
0460 Atropine				83036	HbA1c	

454	Varicose Veins Lwr Ext		
593.81	Vascular Disorder of Kidney, Renal Artery Thrombosis		
459.81	Venous Insuff.		
453.8	Venous Thrombosis Upper Ext		
796.2	White Coat Hypertension		
426.7	Wolff-Parkinson-White Disease		
972.81	Pre Op Cardiovascular VAL OF		
445.82	S/P Stent		
445.1	Renal Dialysis Status		
966.73	Complication of Renal Dialysis Device		

PATIENT INFORMATION :

DATE	TIME	PATIENT	REASON	PRIOR BALANCE
07/27/10	2.00	M.W.	PC/340/302	PAT 0.00 INS 237.00
KEY NO.	DR.#	DOCTOR	LOCATION	D.O.B.
336459	728	PACER/AICO	4VCB PACER AICO	
PATIENT NO.	RESPONSIBLE PARTY	PH#	941 REFERRING DR.	
286715			KOSER MD	
M	F	ADDRESS	CITY/STATE	ZIP CODE
		X		
Ap	OVER 90	OVER 60	OVER 30	CURRENT TOTAL DUE
	0.00	0.00	0.00	237.00 237.00
PT	BC	CS	PAY CHOICE	TODAY'S PAYMENT
5	4	0		
INSURANCE COMPANY	BA	SC	POLICY I.D.	RELATIONSHIP TO INSURED
MEDICARE PART B	Y	I		
BCBS OUT OF STATE	Y	I		
SSN #				
SEL	S	P	C	O
F	P	O	H	T
L	O	I	L	H
E	D	E	R	

Medications	Date	Size	Co	Frequen	Refill
1. VITAMIN E	122700	QD			HAP
2. ZANTAC	092501	150MG	BID		QD
3. THYROID	092501	130MG	QD		BJ
4. COUMADIN	112102	ASD			LK
5. BACTRIN	122302	400MG	1QD		HF
6. LASIX	031003	PRN			RS
7. ASA	031903	PRN			RS
8. CALCIUM	031903	500 XG	2 QAM		RS
9. CARDIZEM	031704	120 XG	QD		90X3/T
10. AMIODARONE	102504	100MG	QD		90X3/T

I hereby authorize my insurance benefits to be paid directly to the above signed physician, realizing I am responsible to pay non-covered services and hereby authorize the release of pertinent medical information to insurance carriers.

Patient Signature

HEAKI & VASCULAR CENTER OF BRADENTON

2101 61st Street West
Bradenton, FL 34209
(941) 761-0448 Fax (941) 761-0235
Billing Inquiries (941) 379-7872
FD #65-1094378

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Joseph N. Peca, MD, FACC
Joseph M. Brancard, MD, FACC
Laura Webb, PA-C
Kimberly French, ARNP
Carol (Kelly) Harrington,

[illegible][illegible]

DATE	TIME	PATIENT	REASON	PRIOR BALANCE	PAT	0.00
07/14/10	11.45	J.S.	PC/REPROGRAM/306/SING	277.55		
TICKET NO.	DR. #	DOCTOR	LOCATION	D.O.B.	TODAY'S CHARGE	
336194	728	PICER/ALCO	RVCB BRADENTON OFFIC			
PATIENT NO.	RESPONSIBLE PARTY	PH#	REFERRING DR.	ADJUSTMENTS		
285731			KOSFELD MD			
S	M	F	ADDRESS	CITY/STATE	ZIP CODE	
ECAP	OVER 90	OVER 60	OVER 30	CURRENT	TOTAL DUE	PT BC CS PAY CHGE
	0.00	0.00	0.00	80.55	277.55	5 1 0
INSURANCE COMPANY	BA	SCIT	POLICY ID.	RELATIONSHIP TO INSURED		
MEDICARE PART B						
BCBS OUT OF STATE						
SSN #						

CPT	Procedure	Frequency	Base CPT Reimbursement
Pacemaker			
93288	Interrogation device evaluation (in person) with physician analysis, review and report, includes connection, recording and disconnection per patient encounter; single, dual, or multiple lead pacemaker system.	dd #10 93734 93731	\$43
Single 93279	Programming device evaluation with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with physician analysis, review and report; single lead pacemaker system.	93735 single pacer reprogramming	\$56 93279
dual 93280	Programming device evaluation with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with physician analysis, review and report; dual lead pacemaker system.	93732 dual pacer reprogramming	\$66 93280
Bi-V 93281	Programming device evaluation with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with physician analysis, review and report; multiple lead pacemaker system.	Bi-V pacer reprogramming	\$77
Implantable Cardioverter Defibrillator (ICD)			
93289	Interrogation device evaluation (in person) with physician analysis, review and report, includes connection, recording and disconnection per patient encounter; single, dual, or multiple lead implantable cardioverter-defibrillator system, including analysis of heart rhythm derived data elements.	93741 93743	\$66
Single 93282	Programming device evaluation with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with physician analysis, review and report; single lead implantable cardioverter-defibrillator system.	93742 single	\$71 93282
dual 93283	Programming device evaluation with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with physician analysis, review and report; dual lead implantable cardioverter-defibrillator system.	93744 dual	\$87 93283
Bi-V 93284	Programming device evaluation with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with physician analysis, review and report; multiple lead implantable cardioverter-defibrillator system.	Bi-V	\$102
Implantable Loop Recorder (ILR)			
93291	Interrogation device evaluation (in person) with physician analysis, review and report, includes connection, recording and disconnection per patient encounter; implantable loop recorder system, including heart rhythm derived data analysis.		\$41
93285	Programming device evaluation with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with physician analysis, review and report; implantable loop recorder system.		\$48
Implantable Cardiovascular Monitor (ICM)			
93290	Interrogation device evaluation (in person) with physician analysis, review and report, includes connection, recording and disconnection per patient encounter; implantable cardiovascular monitor system, including analysis of 1 or more recorded physiologic cardiovascular data elements from all internal and external sensors.	93745	\$32

See important notes on the uses and limitations of this information on page 4.

Latitude 93295

EXHIBIT 10



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Dwight Reynolds, MD, FHRS
President
Heart Rhythm Society

JAN 23 2007
7

7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Dr. Reynolds:

This is in response to your request on behalf of the Heart Rhythm Society (HRS) for a reassessment of the physician supervision requirements for seven non-invasive heart rhythm codes (CPT codes 93731, 93734, 93741-93745). You believe that the physician supervision requirement for the technical component of these services should be changed from direct to general supervision.

We have reviewed the codes and the justification for your request with our medical staff. Based on our review, we believe that the current direct supervision requirement should be retained. The work and practice expense values for these heart rhythm codes comprise physician involvement, stimulation, and assessment. In addition, CPT codes 93742 and 93744 include equipment reprogramming and CPT code 93745 necessitates initial set-up and programming by a physician.

You also note that the 2006 Physician Fee Schedule states that the physician supervision requirements "do not apply" to either the global service or the professional component for the cited codes. According to your interpretation of this denotation, no physician supervision requirements exist for the professional component or for the global service which is comprised of the technical and professional components. On this basis, therefore, HRS contends a change in the physician supervision level from direct to general for the technical component is warranted. This contention is not consistent with the way in which CMS defines the term "concept does not apply" physician supervision level. We use this term in circumstances where the physician rather than any supervising staff would be personally performing the interpretation. Therefore, physician supervision is not relevant and we designate the supervision level for the professional components as "does not apply". Likewise, the global also has a supervision level of "does not apply" since the physician would personally be conducting a portion or component of the service (i.e., the professional component portion).

We regret that we can not provide a more favorable response. We are, therefore, maintaining our current physician supervision levels for the specified codes.

Sincerely,

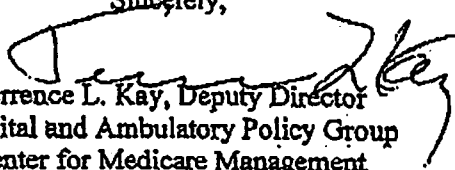

Terrence L. Kay, Deputy Director
Hospital and Ambulatory Policy Group
Center for Medicare Management

EXHIBIT 11

HEALTHCARE AMERICA MEDICAL GROUP, INC.

F#

3501 Cortez Road Bradenton, FL 34210

Telephone: (941) 752-2700

TAX ID# 65-0527738

Enrique Rivera M.D.

Susan L. Gaida A.R.N.P.

MARKS:

SIGNATURE:

DATE: 10/22/09

ACCT#: Patient Name:

DOB:

PRIMARY INS: BCBS PPC

PAT BALANCE: .00

CASH CHECK CHARGE TDAYS Balance:

New Patient

Brief I	99201
Limited II	99202
Intermediate III	99203
Extended IV	99204
Comprehensive V	99205
Post Op Visit	99204
Prolonged Services	99384
Prolonged (Add 30 min)	99385
Established	

Level I	99211
Level II	99212
Level III	99213
Level IV	99214
Level V	99215
Prolonged Services	99384
Prolonged (Add 30 min)	99385
Consultation	

Level I	99241
Level II	99242
Level III	99243
Level IV	99244
Level V	99245

Office Procedures	
EKG w/ Report	93000
Rhythm Strip	93040
IV Labr 20mg / 40mg / 80mg	J1940
Intravenous push / substance / drug	90774
EECP	G0188
Prothrombin Time	88810
Finger Stick	38418

Pacemaker / AICD

ILR Check w/ Reprogram	93285
ILR Check	93281
ILR Check Remote or Tele	93282
Pacer Chk Multi-lead w/ Reprogram	93281
ICD Chk Multi-lead w/ Reprogram	93284
Pacer Check	93288
ICD Check	93289
Pacer Check Remote/Tele	93284 / 93288
ICD Check Remote/ Tele	93285 / 93289
Pacer Reprogram / Dual	93280
ICD Check Dual w/ Re-Program	93283
Pacer Check Single w/ Re-program	93279
ICD Check Single w/ Re-Program	93282

VNUB Closure Procedure

Endovascular Ablation Therapy	98476
2nd & Subsequent Vals	98478
Surgical Supply, Misc.	A4846

Sclerotherapy Treatment

Sclerotherapy Int. Single/Mult vein (Spider)	98489
Sclerotherapy Int. Single Vein	98470
Sclerotherapy Int. Mult Vein Same Leg	98471

Event Monitors

Hook Up	98270
Professional Reading	93272
Technical	93271

EXHIBIT 12

Abnormal EKG
 Abnormal Function Study
 Acute Myocardial Inf Wall
 Angina Pectoris
 Aortic Stenosis Rheumatic
 Aortic Valve Insufficiency
 Aortic Valve Disorder Non-Rheu
 Aortic Valve Disorder
 Arrhythmia / Cardiac Dysrhythmia
 Atheroscl. Lwr Ext Art
 Atrial Fibrillation
 Atrial Flutter
 Atrioventricular Block-Complete
 Bradycardia
 2 AV BLK I
 2 AV BLK II
 Carotid Bruit
 Carotid Occlusion
 Cerebrovascular Disease
 Chest Pain
 Congested Heart Failure
 COPD
 CAD, unsp
 DM - Insulin Dependent
 Dizziness
 DM - Adult Onset

794.31 DVT Femoral Vein
 794.3 DVT Pop. Tibial
 410 Heart Murmur
 413.9 Hypertension
 898 Hypotension
 398.1 Hypercholesterolemia
 424.1 Hyperlipidemia
 424.1 Mitral / Aortic Valve Dis
 427.9 Mitral Stenosis
 440.8 Mitral Valve Insufficiency
 427.31 Mitral Valve Disorder
 427.32 Old MI
 428 Other Malaise + Fatigue
 427.89 Palpitations
 428.19 Peripheral Vascular Dis
 428.12 Pseudoaneurysm - LE
 785.9 CHF Unspec.
 433.1 Unspec Comb Sys/Dias HF
 433.11 Pulmonary Embolism
 788.6 Rheumatic Heart Disease
 428 Ischemic Heart Disease
 498 Cardiomyopathy
 414 Atherosclerosis w/ Claud
 250.01 Pain - Lower Ext.
 780.4 Renal Artery Stenosis
 250 Edema - Lower Ext.

451.11 Atrial Septal Defect
 451.19 Chronic Pulm Heart Dis
 785.2 Shortness Of Breath
 401.9 Sinusoidal Node Dysf SSR
 458.9 S/P CABG / Bypass
 272.0 Superficial Vein Thrombophleb
 272.4 Syncope
 398.9 Tachycardia, Prox Supra Vent
 394.0 Tachycardia, Vent. Proxymal
 394.1 Transient Cerebral Ischemia
 424.0 Tricuspid Insuf
 412 Upper Ext Occlusion
 780.78 Valve Replacement
 785.1 Varicose Vein Lwr Ext
 443.9 Venous Insuff.
 442.3 Complication of Renal Dialysis Dev
 428.0 Renal Failure
 428.40 Renal Insufficiency
 418.19 Chronic Venous Insuff.
 398.90 Venous Leg Pain
 414.8 Swelling in the limb
 426.4 Symptomatic Varicose Leg Veins
 440.21 Heart Valve Replacement
 729.5 Thrombophlebitis
 693.81 Circulating Anticoagulant Disorder
 729.81 Cerebral Atherosclerosis

Other Diagnosis:

JS 44 (Rev. 12/07)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS

United States of America ex rel. John Burns

(b) County of Residence of First Listed Plaintiff Hillsborough
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorney's (Firm Name, Address, and Telephone Number)

Kevin J. Darken, Cohen, Foster & Romine, P.A. 201 E. Kennedy
Blvd., Ste. 1000, Tampa, FL 33602

DEFENDANTS

Medtronic, Inc., Boston Scientific Corp., and St. Jude Medical, Inc.

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE
LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
☐ 2 U.S. Government Defendant
☒ 3 Federal Question (U.S. Government Not a Party)
☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One for Defendant)

- | | PTF | DEF | | PTF | DEF |
|---|----------------------------|----------------------------|---|----------------------------|----------------------------|
| Citizen of This State | <input type="checkbox"/> 1 | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business In This State | <input type="checkbox"/> 4 | <input type="checkbox"/> 4 |
| Citizen of Another State | <input type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business In Another State | <input type="checkbox"/> 5 | <input type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Foreign Nation | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES	
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excl. Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury	PERSONAL INJURY <input type="checkbox"/> 362 Personal Injury - Med. Malpractice <input type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 610 Agriculture <input type="checkbox"/> 620 Other Food & Drug <input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 630 Liquor Laws <input type="checkbox"/> 640 R.R. & Truck <input type="checkbox"/> 650 Airline Regs. <input type="checkbox"/> 660 Occupational Safety/Health <input checked="" type="checkbox"/> 690 Other LABOR <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Mgmt. Relations <input type="checkbox"/> 730 Labor/Mgmt. Reporting & Disclosure Act <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Empl. Ret. Inc. Security Act IMMIGRATION <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 463 Habeas Corpus - Alien Detainee <input type="checkbox"/> 465 Other Immigration Actions	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark SOCIAL SECURITY <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) FEDERAL TAX SUITS <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	<input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 810 Selective Service <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 875 Customer Challenge 12 USC 3410 <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 892 Economic Stabilization Act <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 894 Energy Allocation Act <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 900 Appeal of Fee Determination Under Equal Access to Justice <input type="checkbox"/> 950 Constitutionality of State Statutes
REAL PROPERTY <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	CIVIL RIGHTS <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 444 Welfare <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 440 Other Civil Rights	PRISONER PETITIONS <input type="checkbox"/> 510 Motions to Vacate Sentence Habeas Corpus: <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition			

V. ORIGIN

(Place an "X" in One Box Only)

- ☒ 1 Original Proceeding
☐ 2 Removed from State Court
☐ 3 Remanded from Appellate Court
☐ 4 Reinstated or Recopened
☐ 5 Transferred from another district (specify)
☐ 6 Multidistrict Litigation
☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):
31 U.S.C. § 3729 ex seq.

Brief description of cause:
False Claims Act qui tam action

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23

DEMAND \$

CHECK YES only if demanded in complaint:

JURY DEMAND: ☒ Yes ☐ No**VIII. RELATED CASE(S) IF ANY**

(See instructions):

JUDGE

DOCKET NUMBER

DATE

8-18-10

SIGNATURE OF ATTORNEY OF RECORD

K. J. Darken

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____